NIH Guide
for Grants and Contracts

U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES

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Continued

The NIH Guide is published at irregular intervals to announce scientific initiatives and to provide policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in grants and contracts activities administered by the National Institutes of Health.

Two types of supplements are published by the respective awarding units. Those printed on yellow paper concern contracts: solicitations of sources and announcement of availability of requests for proposals. Those printed on blue paper concern invitations for grant applications in well-defined scientific areas to accomplish specific program purposes.

Have You Moved?
If you present address differs from that shown on the address label, please send your new address to: Grants and Contract Guide Distribution Center, National Institutes of Health, Room B3BN10, Building 31, Bethesda, Maryland 20205, and attach your address label to your letter. Prompt notice of your change of address will prevent your name from being removed from our mailing list.

NOTICE

KEYWORD THESAURUS

Beginning with this issue of the NIH Guide for Grants and Contracts, the announcements are coded to identify areas of interest as listed in the Keyword Thesaurus, a project funded by the National Endowment for the Humanities and the National Science Foundation. NIH has agreed to participate in the project on an experimental basis. A revised version of the Thesaurus is expected to be available by summer of 1984; copies may be ordered from the National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia 22161. The current NTIS Order No. is PB83-211961.

For more information about the project you may write to:

Mr. John A. Rodman
Office of Sponsored Projects
University of Texas at Dallas
P.O. Box 830688
Richardson, Texas 75083-0688

or call Dr. John C. James at the National Institutes of Health at 301-496-7795. Your comments may be addressed either to Dr. James or to Mr. Rodman.

For those who may not have a copy of the 1982 Keyword Thesaurus, the NIH relevant portion is excerpted in the Appendix of this issue. The listing of terms related to biomedical research consists of some terms from the 1982 Thesaurus and terms added by NIH over the past few months. As displayed in individual announcements, the initials "P.T." denote "program " and "K.W." identifies one or more key words corresponding to the subject matter of the program.

The purpose of using the codes and terms of the Keyword Thesaurus is to facilitate distribution of announcements and Requests for Applications (RFAs) to faculty and staff members who have interests in the specific areas listed.

PROGRAM TYPES

02	CAPITAL CONSTRUCTION
04	CENTERS: RESEARCH/DEMONSTRATION/SERVICE
06	CONSULTING/VISITING PERSONNEL
08	CULTURAL OUTREACH
10	CURRICULUM DEVELOPMENT
12	DEMONSTRATION
14	DEVELOPMENT
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0404001 Addiction
0404002 Aging/Gerontonogy
0404003 Alcohol/Alcoholism
1200010 Allergy
1002001 Anatomy
1200020 Anesthesiology
1002002 Animal Breeding and Facilities
1200030 Antibiotics
1200040 Anticonvulsants
1200050 Arthritis
1003001 Atomic & Molecular Structure
1200060 Autoimmunity
1200070 Automated Clinical Analysis
1002003 Bacteriology
0404019 Behavior, Smoking
1200080 Behavioral Medicine
0414003 Behavioral Psychology
0404000 Behavioral/Social Studies/ Other
1200090 Bioassay
1003002 Biochemistry
1200100 Biodegradation
1200110 Bioenergetics
0602000 Bioengineering
1200120 Biofeedback
1200130 Biological Response Modifiers
1002000 Biological Sciences
1200140 Biologicals Resources
1002004 Biology, Cellular
1002006 Biology, Developmental
1007001 Biology, Environmental
1002008 Biology, Molecular
1002009 Biology, Radiation
1200150 Biomaterials
1200160 Biomechanics
0603000 Biomedical Engineering
1200170 Biomedical Research Training
1200180 Biomedical Research, Multidisciplinary
1002012 Biometry
1013004 Biophysics
1200190 Biosynthesis
1200200 Blood/Blood Products/Transfusion
1200210 Bone Marrow
1002013 Botany
1200220 Brain
1002014 Cancer/Carcinogenesis
1200230 Cardiology
1200240 Cardiovascular System
1003003 Chemical Dynamics
1013020 Chemical Physics
1003006 Chemical Synthesis
1003007 Chemistry
1003008 Chemistry, Analytical
1007002 Chemistry, Environmental
1003012 Chemistry, Organic
1003014 Chemistry, Physical
1200250 Chemotherapeutic Agents
1200260 Chemotherapy
0404004 Child Development
0701027 Child/Maternal Health
1200270 Clinical Medicine, General
0414004 Clinical Psychology
1200280 Clinical Trial
1200290 Cloning
0414005 Cognitive Development/ Processes
1200300 Collagen
0701007 Communication Disorders
0403004 Community/Outreach Programs
1004005 Computer Modeling
1004000 Computer Science
1004008 Computer Storage & Retrieval
0503007 Computer-Assisted Instruction
1200310 Connective Tissue
1200320 Contraceptive Development
1200330 Convulsive Disorders
1002015 Cytology
0404007 Death and Dying
0413001 Demography
0701011 Dental Health and Hygiene
0502009 Dental Health Education
0701012 Dentistry
1200340 Dermatology
0414005 Development/Cognitive Processes
0414006 Developmental Psychology
1200350 Diabetes
1200360 Diabetic Retinopathy
1200370 Diagnosis, Medical
1200380 Diagnostic Imaging
1200390 Dialysis
1200400 Digestive System
1200410 Disease Model
1200420 Drug Design
1002016 Ecology
0414007 Educational Psychology
1200430 Electrophysiology
1002017 Embryology
0701029 Emotional/Mental Health
0507002 Emotionally Disturbed Education
1200440 Endocrinology
1007003 Environmental Effects
0701018 Environmental Health
1200450 Enzymology
0701013 Epidemiology
1200460 Etiology
1200470 Eye Diseases
0701014 Family Health/Planning/Safety
0413002 Fertility/Human Reproduction
1200480 Gastroenterology
1200490 Gene Products
1200500 Gene Regulation
1200510 Genetic Manipulation
1002019 Genetics
0404002 Gerontology/Aging
1200520 Growth Factors
0507004 Handicapped Education
0403008 Handicapped/Disabled
0502017 Health and Safety Education
0701016 Health Care
1200540 Health Promotion
0701025 Health Records
0701026 Health Services Delivery
1200550 Hearing
1200560 Hematology
1002021 Histology
0413002 Human Reproduction/Fertility
1200570 Hybridoma
1200580 Hyperplasia
1200590 Hypersensitivity
1200600 Hypertension
1200610 Immune System Disorders
1200620 Immunochemisty
1200630 Immunogenetics
1002023 Immunology
1200640 Immunopathology
1200650 Immunosuppression
1200660 Immunotherapy
1200670 Infectious Agents
1004017 Information Science/Systems
1200680 Inhibitors
1002024 Instrumentation, Biological
1004019 Instrumentation, Medical
1014001 Instrumentation, Scientific
0507005 Learning Disabled Education
0503018 Learning Motivation
1200690 Lipoproteins

1009008	Materials, Polymeric
0701027	Maternal and Child Health
0502024	Medical Education
1200700	Medical Library Resources
1200710	Medical Specialty, Other
1200720	Medicinal Chemistry
1200730	Medicine, Family Practice
1200740	Medicine, Internal
1200750	Membrane Structure/Function
0701029	Mental and Emotional Health
1200760	Mental Retardation
1200770	Metabolic Diseases
1200780	Metabolism
1200790	Metabolism, Lipid
1200800	Metabolism, Mineral
1002027	Microbiology
1200810	Microscopy
0413003	Migration
1200820	Monoclonal Antibodies
1200830	Morphogenesis
1200840	Musculoskeletal System
1002028	Mutagenics
1002029	Mycology
1200850	Natural Products
1200860	Nephrology
1200870	Nervous System
1200880	Neuromuscular Disorders
1200890	Neurophysiology
1002030	Neuroscience
1200900	Neurotransmitters
1200910	Nucleic Acid Sequencing
1200920	Nucleic Acid Structure/ Function
0701032	Nursing
0502028	Nutrition Education
0202022	Nutrition/Dietetics
1200930	Obesity
1200940	Obstetrics-Gynecology
0701034	Occupational Safety & Health
1200950	Oncology
1200960	Opiates
1200970	Opthalmology
1200980	Orthopedics
1200990	Otorhinolaryngology
0701036	Pain
1002032	Parasitology
1201000	Pathology
1201010	Pathophysiology
0701037	Patient Care and Education
1004022	Pattern Recognition (Computer Sciences)
1201020	Pediatrics
1201030	Peptides
1201040	Perinatal Disorders
1201050	Periodontics
1201060	Pharmaceuticals
0701038	Pharmacology
0701039	Pharmacy
1013026	Physics, Radiation
1002034	Physiological Processes
0414011	Physiological Psychology
1002044	Physiology, Vertebrate
1002040	Plant Sciences
1002041	Plant Virology
1007005	Pollution, Air
1007008	Pollution, Water
1009008	Polymeric Materials
0413004	Population Biology
0413005	Population Control
0413000	Population Studies
1201070	Pregnancy
0701041	Preventive Dentistry
0701042	Preventive Medicine
1201080	Prostaglandins
1201090	Prosthetic Device, Heart
1201100	Prosthetic Device, Kidney
1201110	Prosthetic Device, Neural
1201120	Prosthetic Device, Pancreas
1201130	Prosthetic Device, Sensory
1201140	Prosthetic Devices
1201150	Proteins and Macromolecules
1201160	Psychiatry
0414012	Psychobiology
0414000	Psychology
0414013	Psychometrics
1201170	Psychopathology
0701043	Public Health
1002009	Radiation Biology
1013026	Radiation Physics
1201180	Radiology
1201190	Recombinant DNA
0415000	Rehabilitation/Therapy
1002042	Reproduction
1201200	Research Resources, Other
1201210	Respiratory System
1201220	Rheumatic Diseases
1201230	Senile Dimentia
1201240	Serology
0404019	Smoking Behavior
0414014	Social Psychology
0404000	Social Studies
0417000	Sociology
1010013	Statistics
0701046	Stress
1201250	Stroke
1201260	Surgery
1016002	Technology Assessment
1016004	Technology Transfer
1201270	Teratology
0415000	Therapy/Rehabilitation
1201280	Tissue Culture
1007009	Toxicology
1201290	Transplantation Immunology
1201300	Transplantation of Organs
0701048	Trauma
1201310	Tropical Medicine
1201320	Tumor Immunology
1201330	Ultrastructure
1201340	Urology
1201350	Vaccine
1201360	Venereal Diseases
1002044	Vetebrate Physiology
0201058	Veterinary Medicine
1002045	Viral Studies (Virology)
1002046	Vision
1002047	Zoology

NOTICE

NATIONAL SYMPOSIUM ON SCIENTIFIC AND PUBLIC ISSUES THAT ARISE FROM HEALTH RESEARCH INVOLVING VERTEBRATE ANIMALS

P.T. 42; K.W. 0201011, 0701028

A two-day national symposium sponsored by the National Institutes of Health (NIH) will be held at the following location:

The Auditorium
National Academy of Sciences
2100 C Street, NW
Washington, DC

The scheduled dates are April 11-12, 1984. The symposium will convene at 9:00 a.m. each day. The purpose of this national meeting is to develop a broad consensus of understanding and acceptance among the research community as well as the public at large on the imperatives in use of laboratory animals in health research and related animal welfare issues. The symposium will also address Public Health Service (PHS) concerns, policies, and procedures for ensuring humane care and use of laboratory animals involved in health research supported by the PHS.

There will be no registration fee but advance registration no later than Friday, March 30, 1984 is strongly recommended. Those who do not register in advance will be admitted only on a space-available basis. A registration form appears on the last page of this GUIDE.

No parking space is available in the immediate vicinity of the National Academy of Sciences building. The nearest public parking facilities are located on 20th Street, NW between E and F Streets (Colonial Parking), and at 23rd Street and Virginia Avenue, NW (Columbia Plaza). The closest Metro Station (subway) is the Foggy Bottom Station at 23rd and I Streets.

Hotel reservations should be made privately and well in advance by those who plan to attend the symposium,

For further information, contact:

Office for Protection from Research Risks
Building 31 - Room 4B09
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-7005

NOTICE

NIH/FDA REGIONAL WORKSHOPS - PROTECTION OF HUMAN SUBJECTS

P.T. 42; K.W. 0701028

The National Institutes of Health (NIH) and the Food and Drug Administration (FDA are sponsoring a series of workshops on responsibilities of researchers, institutional review boards, and institutional officials for the protection of human subjects in biomedical and behavioral research. The workshops are open to everyone with an interest in research. The meetings should be of special interest to those persons currently serving or about to begin serving as a member of an Institutional Review Board (IRB).

For specific program and registration information, contact one of the individuals listed below or write to:

Roberta H. Garfinkle
Office for Protection from Research Risks
National Institutes of Health
Building 31 - Room 4B09
9000 Rockville Pike
Bethesda, Maryland 20205

NIH/FDA REGIONAL WORKSHOPS

FY 1984

DATE	LOCATION	CONTACT
March 2	Konover Hotel 5445 Collins Avenue Miami Beach, Florida 33140 Telephone: (305) 865-1500 or (800) 327-0555	Mr. Andrew Behrman Research Coordinator Mt. Sinai Medical Center 4300 Alton Road Miami Beach, Florida 33140 Telephone: (305) 674-2197
March 15-16	Auditorium Center for Continuing Education Fifth Floor, Nicholson Tower Oklahoma Children's Memorial Hospital 940 NE 13th Street Oklahoma City, Oklahoma 73190	Mr. Steve Pulik Program Development Specialist University of Oklahoma Health Sciences Center P.O.B. 26901, Library Building Room 115 Oklahoma City, Oklahoma 73190 Telephone: (405) 271-2090

DATE	LOCATION	CONTACT
April 9	The Hyatt Regency New Orleans 500 Poydras Plaza New Orleans, Louisiana 70140 Telephone: (504) 561-1234	Dr. William Gibson Chairman, IRB Office for Research LSU School of Dentistry 1100 Florida Avenue New Orleans, Louisiana 70119 Telephone: (504) 948-8526
April 25	Sheraton Inn 36th and Chestnut Streets Philadelphia, Pennsylvania 19104 Telephone: (215) 387-8000	Ms. Ruth Clark Research Administrator University of Pennsylvania 3451 Walnut Street Philadelphia, Pennsylvania 19174 Telephone: (215) 898-7293
April 27	Mariott Inn 4277 W. 150th Street & I-71 Cleveland, Ohio 44125 Telephone: (216) 252-5333	Dr. Dale Cowan Clinical Professor of Epidemiology and Community Health Department of Oncology Marymount Hospital 12300 McCracken Road Garfield Heights, Ohio 44125 Telephone: (216) 581-0500
May 1	Dana Farber Cancer Institute 44 Binney Street Boston, Massachusetts 02115	Mrs. Joan Rachlin Executive Director Public Responsibility in Medicine and Research (PRIM&R) 132 Boylston Street Boston, Massachusetts 02116 Telephone: (617) 423-4112 or 423-1099
May 21-22	Minneapolis Plaza 315 Nicollet Mall Minneapolis, Minnesota 55401 Telephone: (612) 332-4000	Dr. Jane Boyajian President WorkEthics 2023 Milwaukee Avenue Minneapolis, Minnesota 55404 Telephone: (612) 623-2069 or Ms. Elaine S. Levine Coordinator, IRB St. Paul Ramsey Medical Center 640 Jackson St. Paul, Minnesota 55101 Telephone: (612) 221-2757
Week of September 10	Northern California Bay Area	Further Information to be Announced

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

84-AI-06

COOPERATIVE STUDY OF IMMUNOTHERAPY IN ADULT ASTHMATICS

P.T. 34; K.W. 1200660, 1200670

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Letter of Intent Receipt Date: March 15, 1984
Application Receipt Date: April 15, 1984

The National Institute of Allergy and Infectious Diseases (NIAID) invites applications from investigators interested in participating with the NIAID in a Cooperative Agreement Program designed as a multicenter clinical study seeking to assess the effectiveness of immunotherapy in the management of asthma in adults.

I. BACKGROUND

Since its introduction in 1911, immunotherapy, also called injection treatment, desensitization or hyposensitization, has been used as an aid in the management of certain allergic disorders including asthma, hay fever and reactions to insect stings. It has become standard treatment for patients with rhinitis, allergic to certain airborne antigens especially pollens and molds, whose symptoms do not respond to medication and/or avoidance measures and for patients at risk of having severe reactions to the venoms of certain stinging insects. However, the efficacy of immunotherapy for the treatment of asthma has not been conclusively shown in spite of numerous studies. The reported success rates range from 100 percent to 0 percent depending on the antigen, dose, length of therapy and patient population.

In the past decade reliable objective measures have become available to define and monitor asthma. In the proposed studies, the antigens to be used will be accessible preparations of house dust mite, ragweed and timothy grass pollens which will be compared for content and potency with reagents, currently available for research activities, which are candidates for adoption by the International Union of Immunological Societies (IUIS) as standards. These reagent standards will be supplied by the NIAID.

II. OBJECTIVES AND SCOPE

This RFA is based on the premise that a scientifically sound protocol can be designed to determine if immunotherapy can be beneficial in the treatment of adult asthmatics whose asthma is triggered by and who are specifically allergic to the listed antigens.

The purpose of this RFA is to solicit applications from qualified investigators interested in developing and implementing double-blind placebo-controlled clinical trials to determine the effectiveness of immunotherapy in the management of specific allergen-induced asthma in adults.

Although the final protocol will be developed by consensus among participants during Phase I, applications submitted should contain a plan which could be considered as a model. Proposals for this model should include size of the population required for the study and justification for this size. Applicants need not submit a model for each antigen but may select that or those for which it is believed the institution possesses resources to accomplish the study goal. In order to guide potential investigators in determining the likelihood of their having the requisite study population, the minimal inclusion and exclusion criteria have been proposed and are available in the RFA.

III. STAFF CONTACT

For further information, and a copy of the RFA contact:

Dr. Judith G. Massicot
Program Officer
Immunology, Allergic and Immunologic
Diseases Program
National Institute of Allergy and
Infectious Diseases
National Institutes of Health
Building 31 - Room 7A50
Bethesda, Maryland 20205

Telephone: (301) 496-1886

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR COOPERATIVE AGREEMENT APPLICATIONS: RFA 84-HD-01

COOPERATIVE CLINICAL COMPARISON OF CHORION VILLUS SAMPLING AND AMNIOCENTESIS

P.T. 34; K.W. 1200180, 1200370

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Application Receipt Date: April 15, 1984

The National Institute of Child Health and Human Development (NICHD) invites applications from investigators willing to participate with the NICHD under a Cooperative Agreement Program in a multicenter cooperative clinical study comparing the safety and accuracy of chorion villus sampling (CVS) with amniocentesis.

This clinical study is planned to consist of four sequential phases in which the experience and results from each phase will determine whether or not, and in what manner, the next phase will be undertaken. Phasing of this study is envisioned as follows:

Phase I. Development of a protocol by consensus among the participating centers, preparation of an operations manual, and training of personnel (6 months).

Phase II. Initiation of the project in participating centers.

Phase III. (a) Recruitment of additional centers and completion of enrollment (28 months).

(b) Follow-up of enrolled patients (8 months).

Phase IV. Data analysis and reporting (12 months) to be done in cooperation with a Data Coordinating Center being sought under a separate competition.

The mechanism of support for this study will be a cooperative agreement. Additional information and copies of a more detailed RFA which outlines the clinical center requirements for participation in the proposed study and the method for applying should be obtained from:

Felix de la Cruz, M.D.
Medical Director
Mental Retardation and Development
Disabilities Branch
Center for Research for Mothers and Children
National Institute of Child Health and
Human Development
National Institutes of Health
Landow Building - Room 7C16
Bethesda, Maryland 20205

Telephone: 301 - 496-1383

The deadline for receipt of applications by the NIH Division of Research Grants is April 15, 1984. Logistics and managerial practicality dictate that only applicant institutions in the United States and Canada are eligible.

NOTICE

COOPERATIVE AGREEMENTS FOR COOPERATIVE GROUP OUTREACH PROGRAMS

P.T. 34; K.W. 0403004, 1200280, 1200950

NATIONAL CANCER INSTITUTE

The Division of Cancer Prevention and Control (DCPC), National Cancer Institute (NCI) plans to issue a Request for Application (RFA) directed to NCI-supported clinical cooperative groups for cooperative agreements to strengthen the cancer control programs of currently participating cooperative groups and to encourage the establishment of outreach programs in additional qualified clinical cooperative groups. The program will utilize the existing structure and expertise of the clinical cooperative groups and their members to involve more community physicians in cancer control/clinical research activities, and will make state-of-the-art cancer management available to cancer patients treated in the community by promoting educational opportunities for community oncologists through participation in cooperative group meetings and cooperative group treatment protocols.

Applications will be accepted from only the 18 cooperative groups supported by the Division of Cancer Treatment (DCT). Copies of the RFA will be provided directly to these groups. Cooperative agreement awards will be made for a project period of three years. NCI anticipates making five to eight awards. A total of $5 million has been set aside to fund the awards the initial year.

Interested individuals may obtain copies of the complete RFA and additional information from:

Dorothy MacFarlane, M.D.
Division of Cancer Prevention and Control
National Cancer Institute
Blair Building - Room 7A05
Bethesda, Maryland 20205

Telephone: (301) 427-8708

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

TREATMENT STRATEGIES IN SCHIZOPHRENIA COOPERATIVE AGREEMENT PROGRAM

NATIONAL INSTITUTE OF MENTAL HEALTH

Application Receipt Date: March 1, 1984

The National Institute of Mental Health (NIMH) is launching the Treatment Strategies in Schizophrenia Cooperative Agreement Program to investigate the efficacy of three drug maintenance strategies and their relationship to two psychosocial management strategies in the treatment of schizophrenic patients. Despite improvement in the treatment of schizophrenia during the past two decades, the illness still remains a significant burden in the mental health system.

The purpose of this Request for Applications is to seek cooperative agreement applications from institutions to participate in a common protocol study involving collaboration among investigators at awardee institutions and NIMH staff.

The goals of the Treatment Strategies in Schizophrenia Cooperative Agreement Program are to test whether it is possible to:

- Maximize the benefits of drug treatment and reduce the associated risks by using new drug treatment strategies based on dosage reduction.

- Further reduce risk of relapse and enable the schizophrenic patient to improve independent social functioning and participation in family life by using a family management intervention.

The benefits of medication in the long term treatment of schizophrenia, e.g., reduced risk of relapse, reduction of psychopathology, are well established. However, concerns about the related risk of tardive dyskinesia and the relative lack of improvement of social functioning have led to attempts to improve upon standard pharmacologic treatment.

The proposed multicenter collaborative study will compare standard pharmacologic treatment with two strategies for dose reduction. The study will also test the usefulness of therapeutic enhancement through psychosocial management strategies because dosage reduction alone increases the risk of relapse. The hypothesis is that the addition of a psychosocial strategy will offset the increased risk of relapse incurred by reducing dosage and, in addition, provide improvement in social function.

Copies of the complete RFA may be obtained from:

Ms. Jacqueline Dobson
Parklawn Building - Room 10C-06
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: (301) 443-3524

ANNOUNCEMENT

CANCER EDUCATION PROGRAM

P.T. 16; K.W. 0403004

NATIONAL CANCER INSTITUTE

Application Receipt Dates: June 1, October 1, February 1

The Cancer Education Program, R25 grants, (formerly Professional Oncology Education Program or Clinical Cancer Education Program) announces the continuing receipt of grant applications. Receipt dates are: June 1, October 1, and February 1. Those interested in preparing a grant application should request a copy of the most recent Program Guidelines, including the review criteria, by contacting:

Olga G. Joly, D.D.S., Sc.D.
Program Director
Cancer Education Program, CTB, DCPC
Blair Building - Room 722
9000 Rockville Pike
Bethesda, Maryland 20205

Telephone: (301) 427-8855

NOTICE

CHANGE OF TITLE FOR NICHD MAJOR RESEARCH PROGRAMS

P.T. 34; K.W. 1201040, 1201070, 0701027

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

In order to provide consistency in nomenclature for all Research Center programs supported by the National Institute of Child Health and Human Development (NICHD), the official designation for the Major Research Programs funded by the Center for Research for Mothers and Children under the Specialized Research Grant (P50) mechanism will be changed to Perinatal Emphasis Research Centers (PERC). Consistent with the Congressional endorsement that led to the establishment of the original Major Research Programs, the emphasis in the PERC Program will continue to be on hypothesis-testing multidisciplinary studies directed toward successful pregnancy outcome and to infant survival and well-being. All PERC grants will be organized around problem/need themes in perinatology as designated by NICHD. These grants are not intended to support service, survey, or demonstration projects. However, all PERCs will continue to be established in locations where research can be coordinated with existing programs of health care to facilitate rapid translation of new scientific knowledge into improved health care delivery.

ANNOUNCEMENT

REQUEST FOR APPLICATIONS: RFA

84-HD-02

PERINATAL EMPHASIS RESEARCH CENTER - PERINATAL PHARMACOLOGY AND TOXICOLOGY

P.T. 04; K.W. 1201040, 0701038, 1007009

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Application Receipt Date: April 15, 1984

I. BACKGROUND

The Pregnancy and Perinatology Section (CNPP)-Clinical Nutrition and Early Development Branch of the Center for Research for Mothers and Children (CRMC) of the National Institute of Child Health and Human Development (NICHD) invites grant applications (P-50) for a Perinatal Emphasis Research Center (PERC) in perinatal pharmacology and toxicology. By issuing this Request for Applications (RFA), CRMC is indicating its wish to encourage investigator interest in a specific research area important to its mission and currently not represented in the PERC program.

A PERC grant is used to promote and support multidisciplinary research efforts in areas where (a) knowledge gaps are not being sufficiently addressed by ongoing research, or (b) there are needs to stimulate and intensify efforts in promising research areas. These grants are for the support of hypothesis testing research efforts; they are not intended to support service, survey, or demonstration projects. Research areas for PERC grants have been and will continue to be identified by CRMC in consultation with outside advisors. Through the Perinatal Emphasis Research Center programs for mothers and infants, the Institute has undertaken concerted biomedical and behavioral research efforts directed toward infant survival and well being. The PERC's are organized around problem/need themes and are established where research can be coordinated with existing programs of health care to insure the rapid assimilation of new scientific knowledge into health care delivery. PERC's are located throughout the United States and presently are addressing issues in high risk pregnancies (diabetes, hypertension), prevention of prematurity, and fetal hypoxia.

This program is described in the Catalog of Federal Domestic Assistance No. 13.865, Research for Mothers and Children. Awards will be made under the authority of the Public Health Service Act, Section 301 (42 USC241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to Health Systems Agency review.

Perinatal pharmacology and toxicology has been designated an area of high priority for research support by NICHD. The fetus in utero and the newborn in the intensive care nursery receive many medications; however, the recognition and identification of side effects caused by them is limited. Observed abnormalities are generally attributed to the medical problems that the high risk infant presents. A good understanding of the pharmacology and toxicology of the perinatal period when rapid growth and development occurs is necessary to insure better medical care and decreased incidence of serious complications which may be caused by prescribed therapies.

II. RESEARCH GOALS AND SCOPE

This PERC is proposed to deal with the impact of drugs and chemicals, in vivo and/or in vitro, on maternal, fetal, and neonatal tissues. Investigators are invited to propose studies including neonatal pharmacology, general toxicology, and teratogenesis in both humans and experimental animals. The role of genetic composition, nutrition, duration and stage of gestation, presence of acquired disease in mother and/or developing fetus, and other factors on drug disposition and effect are of interest. The impact of normal and abnormal placental development on the distribution and effect of pharmacological agents in mother and fetus and on placental transfer may be considered. The impact of fetal exposures on neonatal responses; and short- and long-term differential consequences of exposures during labor, delivery, the postpartum period, or during lactation are areas in which studies would be welcomed. Studies of changes in dose-response relationships, route of administration, binding and distribution, and organ-specific metablism and excretion would be of interest, as are the intracellular distribution and action of agents. The above considerations may encompass both maternal drug administration and therapy and/or treatment of the fetus. Development of methodologies to enable these studies is encouraged including non-invasive procedures, micro-analytical techniques, and methods which minimize risks to the maternal-fetal unit.

III. MECHANISM OF SUPPORT

Perinatal Emphasis Research Center grants (P-50) will be supported through the customary grant-in-aid mechanism. Awards will be made initially for a period of not less than three years and not more than five years, with an option for renewal. To be eligible for award as a PERC, an application should conform to the guidelines for center grants which may be requested from NICHD staff (contact Dr. Charlotte Catz, 301-496-5575).

The receipt date for this single-competition announcement is April 15, 1984. It is anticipated that any award made under this announcement will have a start date on or before September 30, 1984. NICHD contemplates making a single award and has set aside $500,000 for the first year support.

IV. REVIEW PROCEDURES AND CRITERIA

Applications submitted in response to this RFA will be evaluated for scientific merit by an NICHD research review committee. A site visit is not a prerequisite for review. The second level review will be made by the National Advisory Child Health and Human Development Council.

Factors to be considered in evaluating a PERC grant application are:

1. Responsiveness of the research program to the mission of the CRMC.

2. Significance of the proposed research program to the overall goal of the PERC.

3. Suitability of the program's central theme for a cooperative research effort.

4. Multidisciplinary scope of the program and provision for coordinating the research projects and core units.

5. Leadership and scientific stature of the program director and his/her ability to meet the program's demands of time and effort.

The review of the projects and core units will consider:

1. Scientific merit of each project and the relation of the project to the central theme of the overall program.

2. Technical merit and justification of each core unit.

3. Qualifications, experience, and commitment of the investigators responsible for the research projects or core units and their ability to devote the required time and effort to the program.

4. Appropriateness of the total budget and budgetary requests for the individual projects and core units.

5. As appropriate, the adequacy of the means proposed for protecting against risks to human subjects, animals, and/or environment.

6. Participation of a suitable number of responsible, experienced investigators.

7. Academic and physical environment as it bears on patients, space, and equipment, and on the potential for interaction with scientists from other departments and institutions.

8. Arrangements for internal quality control of ongoing research, the allocation of funds, day-to-day management, contractual agreements, and internal communication and cooperation among the investigators in the program.

9. Presence of an administrative and organizational structure conducive to attaining the objectives of the proposed program.

10. Institutional commitment to the requirements of the program.

V. METHOD OF APPLYING

Applications must be submitted on form NIH-398 which includes form HHS-596, Protection of Human Subjects. The conventional presentation format for regular

research grant applications should be used, with care taken to fulfill the points Pidentified under review criteria. Applications will be reviewed by NIH staff for responsiveness to the RFA. Applications judged to be non-responsive will be returned.

The phrase **"PERC-Perinatal Pharmacology and Toxicology, 84-HD-02"** should be typed in item 2 on front page of the grant application form. The original and four copies of the application should be sent or delivered to:

Application Receipt Office
Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

Two copies should be sent or delivered to:

Associate Director for Scientific Review
National Institute for Child Health
and Human Development
National Institutes of Health
Landow Building - Room 6C08
Bethesda, Maryland 20205

Investigators wishing to apply for a PERC grant (P-50) are encouraged (but not required) to submit a letter of intent to the Director of the Center for Research for Mothers and Children by March 1, 1984. The letter of intent, not to exceed three single-spaced typewritten pages, should outline the proposed program of research, name the principal investigators of the individual projects, and state the qualifications of the applicant institution. It should be submitted to:

Dr. Sumner J. Yaffe
Director
Center for Research for Mothers and Children
National Institute of Child Health
and Human Development
Landow Building - Room 7C03
Bethesda, Maryland 20205

The letter of intent will be reviewed to determine the proposal's appropriateness for the NICHD's PERC program and whether the institution appears to meet the eligibility requirements for center status. Detailed guidelines are found in "NICHD Research Centers Programs" which can be obtained from the NICHD staff contact. Staff will review the letter and contact each applicant.

For further information, potential applicants may write to Director, CRMC or call Dr. Charlotte Catz, Head, Pregnancy and Perinatology Section, Clinical Nutrition and Early Development Branch, Center for Research for Mothers and Children, National Institute of Child Health and Human Development, on (301) 496-5575.

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA 84-DE-03

ORAL HEALTH AND BEHAVIOR RESEARCH CENTERS

P.T. 34, 04; K.W. 0701041, 1200080, 0701011

NATIONAL INSTITUTE OF DENTAL RESEARCH

Application Receipt Date: June 15, 1984

The National Institute of Dental Research (NIDR) invites applications for one or more new clinical research centers studying linkages between behaviors and oral health. The NIDR will initiate support for multidisciplinary centers of research excellence in an effort to accelerate scientific progress related to oral health and behavior, as well as to develop an appropriate scientific foundation for intervention studies aimed toward improving oral disease prevention and treatment.

The main objective of the Oral Health and Behavior Research Centers will be to conduct fundamental and applied multidisciplinary research directed toward determining behavioral and social aspects of oral disease epidemiology, etiology, prevention, diagnosis, or treatment. Specifically, the centers should develop research programs directed toward addressing at least two of the following broad objectives:

1. Identify behavioral and social risk factors associated with the incidence and prevalence of caries, periodontal diseases, congenital or acquired craniofacial anomalies, temporomandibular joint dysfunction, or other related oral diseases or conditions, as well as socio-behavioral or psychophysiological factors associated with the development or progression of such diseases/conditions.

2. Develop behaviorally based interventions aimed toward establishing at least several of the following:

   - earlier, more cost-effective, or otherwise improved approaches aiding in the diagnosis of oral diseases or conditions.

   - improved approaches for identifying or intercepting oral diseases at an earlier stage and for reducing negative functional or psychosocial impacts associated with oral diseases/conditions.

This program is described in the Catalog of Federal Domestic Assistance No. 13.844, Pain Control and Behavioral Studies. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under the PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to Health Systems Agency review.

- improved approaches for producing sustained adherence to preventive or therapeutic regimens.

- improved behavioral approaches for increasing both the acceptability and health-enhancing impacts of dental services.

3. Evaluate the qualitative and quantitative impacts of the interventions developed, assessing both the costs and outcomes of the methodologies employed and their specific impacts upon measures of oral health status (including, where feasible, both short-term and long-term measures of oral health status).

The substance of each research program may vary according to local expertise, interest, resources, and recruitment possibilities, but the projects developed by each center must relate to the above objectives. Applicants should attempt to develop a unique program which is complementary to, rather than duplicative of, ongoing research. The Institution must be willing to make a commitment of resources and staff to ensure the development, operation, and function of the proposed center.

Copies of the complete RFA and additional information may be obtained from:

Dr. Patricia Bryant
Craniofacial Anomalies, Pain Control
and Behavioral Research Branch
Extramural Programs
National Institute of Dental Research
Westwood Building - Room 510
Bethesda, Maryland 20205

Telephone (301) 496-7491

ANNOUNCEMENT

REQUEST FOR APPLICATIONS: RFA

84-DE-04

NATIONAL RESEARCH SERVICE AWARDS FOR INSTITUTIONAL, POSTDOCTORAL TRAINING PROGRAMS IN CARIES RESEARCH

P.T. 44; K.W. 0701041, 1200170

NATIONAL INSTITUTE OF DENTAL RESEARCH

Application Receipt Date: June 15, 1984

The National Institute of Dental Research (NIDR) supports research and development projects designed to develop methods to prevent and ultimately eliminate dental caries as a public health problem. Coronal caries affects two-thirds of U.S. school children and is the leading cause of tooth loss in children and young adults. The progressive tooth destruction characteristic of the disease results from interactions among three primary factors: oral bacteria, capable of fermenting dietary substrates to produce acid, which dissolves the tooth enamel of a susceptible host. Interventions directed at any one of these three factors prevent the disease. Social and behavioral factors are also important in determining caries incidence and the success of preventive measures. Research strategies are dictated by the multi-factorial etiology of the disease. They focus on combatting the microbial agent, increasing tooth resistance and modifying the diet. Efforts are also being made to improve the delivery and acceptance of caries preventive methods. Very little is known about the etiology and methods for prevention of secondary and root caries, which affect adults and may be increasing in prevalence.

Investigation of the diverse factors implicated in caries etiology and the development and evaluation of preventive methods necessitates participation by investigators from numerous disciplines. These include chemists, microbiologists, immunologists, pharmacologists, nutritionists, behavioral scientists, statisticians, epidemiologists and dentists experienced in conducting clinical trials and demonstration programs. In addition, there is a need for individuals with capabilities spanning several of these disciplines. Applications are invited from U.S. organizations for Institutional National Research Service Awards (NRSA) to provide post-doctoral training in caries research. Successful applicants will be expected to provide all trainees with didactic instruction in dental and oral anatomy and physiology, composition and functions of saliva, microbial and dietary factors in caries etiology, use of animal models in caries research, principles of epidemiology and biostatistics and the design and conduct of clinical trials. The institutions must have sufficient ongoing, funded research to offer supervised research

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This program is described in the Catalog of Federal Domestic Assistance No. 13.840, Caries Research. Awards will be made under the authority of the Public Health Service Act, Section 472 (42 USC 2891-1), and administered under PHS grants policy and Federal Regulations 42 CFR Part 66.

opportunities in at least two of these areas. Close cooperation between the training program director, faculty anmd trainees and NIDR staff will be expected to ensure that these objectives are met.

Funds may be requested for training a maximum of six individuals during a five-year project period. Subsequent support will be contingent upon program needs and the applicant's performance. Trainees should be clinically qualified (D.D.S., D.M.D.) or possess Ph.D., M.D., or D.V.M. degrees. Consideration should be given to integrating the training with degree (M.S., M.P.H., Ph.D.) or clinical residency programs, where appropriate. However, the award may only be used to support that portion of the degree or residency program which is required for training in caries research. The current stipend for postdoctoral trainees is $14,040-$19,716, depending on the number of years of relevant experience. Trainee tuition, fees, meeting travel, and medical insurance may be requested. Each trainee may be supported for three years. Trainees are subject to NRSA payback provisions. Institutional costs, up to $2,500 per year, per trainee may be requested to defray training related expenses, such as staff salaries and research supplies.

Because of funding limitations and the specialized nature of the training it is probable that only one new award will be made. Awards resulting from this RFA are contingent upon receipt of appropriated funds. The earliest start date will be July 1, 1985. Applications will be evaluated initially by the NIDR Special Grants Review Committee and subsequently by the National Advisory Dental Research Council early in 1985. Results of the competition will be announced shortly thereafter. This RFA may be reissued at a later date.

There will be a single competition with a receipt date of June 15, 1984. Applications received after that date will be accepted at the discretion of the Division of Research Grants (DRG) staff. Applicants should use form PHS 6025, which is available in most institutional business offices or from the DRG, NIH. The face page must be labeled **"In response to RFA 84-DE-04."** The original and six copies should be mailed to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

Applications judged to be nonresponsive to this request will be returned to the applicant. To ensure that applications will be responsive to NIDR interests, potential applicants are strongly urged to submit a brief letter of intent providing an outline of the proposal on or before April 30, 1984. The letter of intent is not binding nor is it a prerequisite for acceptance of applications. Letters of intent, questions concerning this RFA, and requests for NRSA institutional grant announcements should be addressed to:

John D. Townsley, Ph.D.
Chief, Caries and Restorative Materials Research Branch
Extramural Programs
National Institute of Dental Research
Westwood Building - Room 522
Bethesda, Maryland 20205

Telephone: (301) 496-7884

ANNOUNCEMENT

CLINICAL INVESTIGATOR AWARD

P.T. 34; K.W. 1200240, 1200200, 1200270

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Dates: February 1, June 1 and October 1

I. PURPOSE

The National Heart, Lung and Blood Institute (NHLBI) announces the availability of Clinical Investigator Awards. The clinical investigator award program is intended to:

- o encourage newly trained clinicians to develop clinical and basic research interests and skills in the areas of cardiovascular, pulmonary, or blood diseases and the blood banking sciences.
- o increase the pool of physician investigators in the areas of cardiovascular, pulmonary, or blood diseases and the blood banking sciences.

These awards provide the opportunity for clinically trained physicians with a commitment to research to develop into independent biomedical research investigators.

The award will enable candidates to undertake five years of special study and supervised experience tailored to individual needs with a sponsor (or sponsors) competent to provide research guidance. This award is intended to cover the transition between postdoctoral experience and a career in independent investigation. The clinical investigator award differs from the National Institutes of Health (NIH) Research Career Development Award (RCDA) in that it seeks to develop research ability in individuals who have completed their clinical training rather than to promote the further development of research skills of individuals already demonstrating significant research achievement.

II. PROVISIONS OF THE AWARD

The clinical investigator awardee will be supported for a period of five years. Support is based on a full-time, twelve-month appointment.

This program is described in the Catalog of Federal Domestic Assistance numbers 13.837, 13.838, and 13.839. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under the PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to Health Systems Agency review.

The awardee will be provided salary support of up to $30,000, plus fringe benefits. The actual salary must be consistent with the established salary structure of the institution for persons of equivalent qualifications, experience, and rank. Salary supplementation is permitted from non-NIH funds.

Up to a total of $10,000 annually may be provided for supplies, equipment, travel, etc., necessary for pursuit of the awardee's research program. An appropriate sponsor must assume responsibility and provide guidance for the development of the candidate's research program.

Institutions may apply for awards on behalf of named individuals meeting the criteria for this award. Evidence of the commitment of the institution and sponsors to the candidate's research and career development is to be included in the application.

The grant will be made annually to the awardee's parent institution for each of the five annual budget periods. Funds will be provided for the reimbursement of actual indirect costs at a rate up to, but not exceeding, 8 percent of the total direct costs of each award, exclusive of tuition, fees, and expenditures for equipment.

III. APPLICATION

Applications must be submitted on form PHS 398 which is available at grantee institutions. The application should be clearly labeled **"NHLBI CLINICAL INVESTIGATOR AWARD PROGRAM."** Instructions for preparing the CIA applications using the PHS 398 form may be requested from the individuals listed in Section IV. of this announcement.

The original and four complete copies of grant applications should be mailed to the following:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

Two (2) additional copies should be mailed at the same time to the Executive Secretary, Research Manpower Review Committee.

Applications by	will have initial review the following	Council review in	The earliest award award date will be
February 1	June	October	December 1
June 1	November	February	April 1
October 1	March	May	July 1

IV. NHLBI STAFF CONTACTS

Inquiries about the program and requests for program guidelines and instructions should be directed to:

Research Training and Development Officer
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
Federal Building - Room 5A08
Bethesda, Maryland 20205

Telephone: (301) 496-1817

Research Training and Development Officer
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
Federal Building - Room 3A08

Telephone: (301) 496-1724

Research Training and Development Officer
Division of Lung Diseases
National Heart, Lung, and Blood Institute
Westwood Building - Room 6A12
Bethesda, Maryland 20205

Telephone: (301) 496-7668

Letters of reference and inquiries regarding review procedures should be directed to:

Executive Secretary
Research Manpower Review Committee
National Heart, Lung, and Blood Institute
Westwood Building - Room 550
5333 Westbard Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-7361

ANNOUNCEMENT

THE NCI CLINICAL INVESTIGATOR AWARD

P.T. 34; K.W. 1002014, 1200950, 1201180, 1200270

NATIONAL CANCER INSTITUTE

Application Receipt Dates: June 1, October 1, February 1

I. SUMMARY AND PURPOSE

The National Cancer Institute (NCI) announces the availability of Clinical Investigator Awards for the purpose of developing physician-researchers in basic and applied cancer sciences. The initiation of this award is intended to encourage recently trained, highly qualified physician-investigators to undertake careers in cancer research. The award is prompted by the chronic shortage of physician-investigators, particularly surgical oncologists, therapeutic radiologists, diagnostic radiologists, preventive oncologists, physiatrists, nutritionists, and epidemiologists. It is expected to facilitate the awardee's transition to independent basic or applied research. The award will enable successful candidates to investigate for up to three years a defined cancer problem under the guidance of an active researcher who has the knowledge, background and research experience required to be a mentor in that field.

II. ELIGIBILITY

A. Candidate

The award is designed to provide intensive, supervised research experience for physicians. Thus, candidates are restricted to those holding the M.D. or D.O. degree. A candidate will not qualify if he/she is in any of the following categories:

- a person having more than seven years of postdoctoral experience at the time of award;
- a person having previous independent NIH research support or its equivalent from another source;

This program is described in the Catalog of Federal Domestic Assistance No. 13.398, Cancer Research Manpower. Award will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 74. This program is not subject to Health Systems Agency review.

- o a person having less than two years total postdoctoral clinical experience at the time of the award;

- o a person holding a Ph.D. or comparable research degree.

Candidates should have broad clinical training, should demonstrate individual competence in clinical activities, and should show research potential in the chosen area of interest. Candidates must provide evidence of a serious intent for engaging in research and/or academic careers.

Only United States citizens, nationals or permanent residents may be presented as candidates for this award.

B. Institution

The sponsoring institution must have a strong, well-established research program in the candidate's area of interest, and experienced faculty members in the clinical and basic departments relevant to the candidate's proposed training. The institution must include a plan for the candidate's research and academic development. Only domestic institutions are eligible.

C. Preceptor

The candidate's primary preceptor must be a competent investigator in the area of the candidate's proposed research activity. The preceptor must be active currently as an investigator, and must be prepared to provide personally much of the candidate's research supervision. The award is intended to provide an intensive, supervised research experience for the successful candidate.

III. PROVISIONS OF THE AWARD

The Clinical Investigator Award is made for a maximum nonrenewable and nontransferable period of three years. Support is based upon a full-time, twelve-month appointment. The award will provide salary support not to exceed $30,000 annually from NCI funds for the three-year period. The actual salary must be consistent with the established salary structure of the grantee institution for persons of equivalent qualifications, experience, and rank. This salary may be supplemented by the grantee institution in conformance with PHS policy. Up to a total of $10,000 annually will be provided for supplies, equipment, travel, etc., which are necessary for pursuit of the awardee's research program. Funds will be provided for the reimbursement of indirect costs at a rate not to exceed eight percent of the total allowable direct costs. When requested, the grantee nstitution's share of the fringe benefits may be paid as a direct cost (if not treated as an indirect cost) on that portion of the employee's salary provided by the NCI Clinical Investigator Award.

It is expected that the candidate will spend at least 75 percent of his/her time in research during the period, with the remainder being divided among other activities such as teaching, pertinent clinical training, research training, and academic studies. An appropriate sponsor must assume responsibility and provide guidance for the research development in the chosen areas.

Institutions may apply for awards on behalf of named individuals meeting the above criteria. It is not essential for the applicant institution to commit itself in the application to eventual placement of the candidate on its permanent, full-time faculty, but it is expected that institutions will choose candidates who will be able to meet the criteria for making that decision. Evidence of commitment to the candidate's research development must be provided by the institution.

Candidates for this award may not concurrently apply for a Research Career Development Award, an Academic Award or a New Investigator Research Award.

Candidates must be nominated by an institution on the basis of qualifications, interests, accomplishments, motivation and potential for an academic or research career. Candidates must have one or more sponsors at the institution who are recognized as accomplished researchers or teachers in the candidate's area of proposed development. The sponsor(s) must provide (1) his/her concept of a development and research plan for the candidates; (2) his/her updated curriculum vitae with a complete bibliography and research support; and (3) a letter indicating willingness to provide guidance and support for the award's duration.

Candidates must provide a full description of the proposed research and career development plan for the three-year period of the award. The candidate must be prepared to commit full-time effort to the objectives of this award.

Candidates must agree to inform the NCI annually for a period of ten years subsequent to completion of the award about academic status, publications, and research grants or contracts received.

IV. REVIEW CRITERIA

Applications will undergo initial merit review in the Grants Review Branch, Division of Extramural Activities. NCI. Secondary review will be by the National Cancer Advisory Board. Criteria for review include:

- The candidate's potential for a career in independent research;
- The candidate's commitment to a research career;
- The eligibility of the candidate as defined in the program announcement;
- The overall merit of the candidate's three-year plan for research and the development of research skills;
- The quality of the candidate's clinical training and experience;
- The institution's ability to provide quality facilities, resources, and opportunities necessary to the candidate's research development;
- Presence of highly trained faculty in clinical and basic science departments relative to the area of study; and
- The ability and plans of the sponsor (or sponsors) who will provide the candidate with the guidance necessary for career development in research.

V. HOW TO APPLY

Please read a copy of the "Program Guidelines" before applying for one of these awards. These are obtainable from Dr. Mayyasi. An application for this award should be made on form PHS 398 (Rev. 5/82). Application receipt dates are: February 1, June 1, and October 1. Please send the original and six (6) copies to the Division of Research Grants as indicated in the instructions furnished in the application kit. Questions should be addressed to:

Sami A. Mayyasi, Ph.D.
Program Director
Clinical Investigator Awards
Division of Cancer Prevention and Control
Blair Building - Room 717
Bethesda, Maryland 20205

Telephone: (301) 427-8898

ANNOUNCEMENT

VASCULAR AND LYMPHATIC INVASION IN BREAST CANCER

P.T. 34; K.W. 1002021, 1200370

NATIONAL CANCER INSTITUTE

The Breast Cancer Section of the Organ Systems Program, Division of Resources, Centers, and Community Activities, National Cancer Institute (NCI), sponsors both fundamental and clinical research grants and contracts in a continuing effort to improve our ability to diagnose and to estimate prognosis in cases of breast cancer. In the past several years, it has been shown that vascular and/or lymphatic invasion is an important correlate of survival. This request for applications is intended to encourage submission of investigator-initiated research grant proposals designed to facilitate the identification of intravascular and intralymphatic tumor growth in histological sections.

I. BACKGROUND

The importance of tumor extension into vascular and/or lymphatic channels has been recognized for years. However, in the breast, pathologists have always had difficulty in distinguishing intravascular or intralymphatic tumor growth, even with the use of special histochemical methods, such as elastic tissue stains. These stains are of no use in differentiating tumor growth in venules, capillaries or lymphatics, since these small vessels do not have elastic tissue. Larger vessels, such as veins and small arteries which have an elastic lamina often cannot be distinguished from mammary ducts, especially in the areas of periductal elastosis. Furthermore, vascular or lymphatic channels may be difficult to recognize because of fibrosis, which often occurs in breast cancer, shrinkage artifacts from fixation, or inflammation which obscures the vascular space.

Thus in order to improve the detection and quantitation of vascular and lymphatic invasion, especially in Stage 1 cancers, the Breast Cancer Section is interested in 1) developing histochemical, immunohistochemical or other histologic methods that could be used routinely and that would differentiate intravascular and intralymphatic extension from the remainder of the tumor mass, or 2) determining other histologic factors that would correlate with the extent of invasion. With further clinical pathological studies, it should be possible to determine if these methods can provide a useful estimate of prognosis and even serve as a guide for therapy.

This program is described in the Catalog of Federal Domestic Assistance No. 13.394 - Cancer Detection and Diagnosis Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to Health Systems Agency Review.

II. MECHANISM OF SUPPORT

The mechanism of support will be the traditional research grant. Policies that govern research grant programs of the National Institutes of Health will prevail. The award of grants pursuant to this request for grant applications is contingent upon receipt of proposals of high scientific merit and the availability of appropriated funds.

III. APPLICATION AND REVIEW PROCEDURES

A. Assignment of Applications

Applications will be received by the Division of Research Grants (DRG), National Institutes of Health (NIH). DRG will refer the proposals to the appropriate Study Section for scientific review, and will assign them to the NCI for possible funding and management. These decisions will be governed by normal programmatic considerations as specified in the DRG Referral Guidelines.

B. Review Procedures

Applications in response to this announcement will be reviewed in accordance with the usual NIH peer review procedures (Study Section). Factors considered in the scientific merit evaluation of each application will include an assessment of the importance of the proposed research problem, the novelty and originality of approach, the training experience and research competence of the investigator(s), the adequacy of experimental design, the suitability of the facilities, and the appropriateness of the requested budeget relative to the work proposed.

C. Deadlines

Applications will be accepted in accordance with the usual dates for new applications on an indefinite basis: March 1, July 1, and November 1.

ANNOUNCEMENT

PERSISTENT VIRAL INFECTIONS - ALZHEIMER'S DISEASE

P.T. 34; K.W. 1002045, 1200670, 0404002, 1200460

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

NATIONAL INSTITUTE ON AGING

The National Institute of Allergy and Infectious Diseases (NIAID), the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) and the National Institute on Aging (NIA) invite applications for regular research grants on the subject of persistent viral infections possibly associated with, or models for, chronic human diseases such as Alzheimer's disease.

Viral infections have been associated with several chronic diseases of man such as recurrent herpes and chronic persistent hepatitis as well as the spongiform encephalitides. Viral etiologies also have been hypothesized for acquired immune deficiency syndrome (AIDS), juvenile onset diabetes and certain chronic degenerative diseases such as Alzheimer's. How viruses can persist in cells, escape immune surveillance and alter vital cellular functions has not been well elucidated. Progress has been slow partly due to the lack of adequate experimental hosts for study and, in most cases, failure to isolate and cultivate the putative pathogens.

The interests of NIAID are directed toward understanding in depth mechanisms by which viruses can persist within fully differentiated mammalian cells or tissues for long periods in immunocompetent individuals and cause alterations of specialized cell functions, autoimmune reactions or cytopathology.

The programmatic interests of NINCDS include infectious bases of neurological disorders with particular emphasis upon persistent infections of cells and tissues of the nervous system and the biology of viral neurotropism.

The NIA is interested in supporting research on infectious diseases that involve the aging process or that present problems for the aging.

Although the programmatic goals emphasize diseases of man, experimental systems in other mammalian hosts may be more appropriate to investigate the basic processes of pathogenesis. Model systems that relate to known chronic human diseases are sought for study.

This program is described in the Catalog of Federal Domestic Assistance No. 13.856, Microbiology and Infectious Diseases Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 73-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52. This program is not subject to Health Systems Agency review.

Another goal of this research program is to identify biological markers that are predisposing to or diagnostic of specific chronic diseases, such as Alzheimer's, for which a transmissible etiologic agent may be suspected but not yet known.

APPLICATION SUBMISSION AND REVIEW

Eligibility: Universities, medical colleges, hospitals, and laboratories of other public, private or for profit institutions are eligible. Application receipt dates for new applications are the regular receipt dates of March 1, July 1 and November 1. The earliest possible award date is approximately nine months after the receipt date. Applicants should use the regular research grant application form PHS 398 that is available at most institutional business offices or from the Division of Research Grants (DRG), NIH.

To identify responses to this announcement, check "yes" and put "Persistent Viral Infections, Alzheimer's Disease" under Item 2 of page 1 of those grant applications relating to the topic of this announcement. The completed application should be mailed to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
5333 Westbard Avenue
Bethesda, Maryland 20205

The DRG will assign applications for technical review according to the NIH process for regular grant applications. Assignments for funding decisions will follow programmatic guidelines established for NIH.

Inquiries prior to submission may be directed to:

William P. Allen, Ph.D.
BVB, MIDP, NIAID
Westwood Building - Room 736
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-7453

or

Zaven S. Khachaturian, Ph.D.
PAB, BRCMP, NIA
Building 31C - Room 5C27
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-9350

or

A. P. Kerza-Kwiatecki, Ph. D.
DADDP, NINCDS
Federal Building - Room 708A
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-1431

ANNOUNCEMENT

THE BIOLOGY OF NEURODEGENERATIVE DISORDERS

P.T. 34; K.W. 1002008, 1002030, 1200900, 0701007

NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

I. PURPOSE

The National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) invites qualified investigators to submit grant applications for the support of research on the biological bases of neurodegenerative disorders. These include motor neuron diseases (e.g.: amyotrophic lateral sclerosis, progressive bulbar palsy), basal ganglia disorders (e.g.: Parkinson's and Huntington's disease), heredofamilial ataxias, Alzheimer's disease, and neurosensory disorders such as presbycusis and familial deafness. Recent progress in the fields of molecular genetics, immunology, biochemistry, and anatomy, and technical developments in Positron Emission Tomography and Nuclear Magnetic Resonance imaging have created new opportunities for understanding the bases of the premature nerve cell death and system degenerations that underlie such degenerative disorders of the nervous and communicative systems.

The proposed program of grant support was designed in honor of Senator Jacob Javits, to recognize his vigorous and effective support of neuroscience research as the best hope for the eventual conquest of these degenerative neurological and communicative disorders.

II. BACKGROUND

Neurodegenerative disorders result from the premature death of nerve cells in the brain and spinal cord: anterior horn cells for motor neuron disease, dopaminergic neurons of the substantia nigra in Parkinsonism, the caudate nucleus in Huntington's disease, cholinergic neurons in the basal forebrain in Alzheimer's disease, and cells and tracts of the acoustic system in degenerative hearing disorders.

This program is described in the Catalogue of Federal Domestic Assistance Number 13.854, Biological Basis Research. Grants will be awarded under the authority of the Public Health Service Act, Title IV, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grants policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This Program is not subject to Health Systems Agency review.

Such neuronal degeneration has been attributed to genetic defects, transmissible infectious agents, toxic substances, immune system disorders and other as yet undetermined mechanisms. New research techniques have created opportunities for further exploration.

- The recent progress in the molecular genetics of Huntington's disease opens the door to presymptomatic and prenatal diagnosis of this disorder as well as for the identification and cloning of the defective gene itself. Similar techniques could be applicable to other genetic disorders such as Friedreich's ataxia, familial Alzheimer's disease, and hereditary deafness.

- The ability to demonstrate neurotransmitter receptors in the living human brain using positron emission tomography permits the study of receptors during the course of a disease or while a patient is receiving therapy.

- The demonstration that grafting neurotransmitter synthesizing tissues into animal brains may reverse the effects of basal ganglia lesions could have important therapeutic implication for disorders resulting from the failure of focal collections of neurons to secrete neurotransmitters.

- Immunocytological techniques can now be combined with anatomical and biochemical methodologies to trace pathways through the nervous system and to identify transmitter substances and their receptors.

- Many different peptides, originally characterized in non-neural tissues, continue to be identified and localized in various brain regions. Specific receptors for some peptides have been identified. Neuropeptides have been shown to affect such diverse physiological functions as pain, appetite, blood pressure and electrolyte balance. Alterations in concentration of specific brain peptides have been reported in Alzheimer's and Huntington's disease. These alterations may be useful as possible markers for neurodegenerative disorders. Their role in the etiology of such disorders is still unknown.

III. OBJECTIVES AND SCOPE

This solicitation is prompted by the need for an expanded research effort to gain greater insights into the mechanisms of neuronal and system degenerations. Research is encouraged to develop methods for elucidating the mechanisms of nerve cell death through the application of new techniques in neurobiology. Such research could involve, for example:

- Identification of naturally occurring and experimentally induced animal models of neurodegenerative disorders.

- Development of molecular genetic techniques for the identification of genetic markers for neurodegenerative disorders, cloning the defective gene(s), and identification of the mechanism by which the gene product causes nerve cell degeneration.

- Development of techniques to visualize transmitters, receptors or neuronal activity in living brains and the application of imaging technology (PET and NMR) to studies of nerve cell degeneration.

- Investigation of viral induced degeneration of nerve cells.

- o Investigation of the role of peptides and other neurotransmitters in neurodegenerative disorders.

- o Studies of developmental processes to elucidate the mechanisms of neuronal death that occurs in the course of normal development.

- o Studies of degeneration and regeneration of nerve cells in the olfactory system.

These are only examples of possibly fruitful research areas and should not be viewed as exclusive.

IV. APPLICATION SUBMISSION AND REVIEW

Application receipt dates for new applications are the regular application receipt dates of March 1, July 1, and November 1. Applications received after any one receipt date are considered and reviewed together with those received by the next receipt date. The earliest possible award date is approximately nine months after the receipt date. Applicants should use the regular research grant application form PHS-398, which is available at the applicant's institutional application control office or from the Division of Research Grants (DRG) National Institutes of Health (NIH).

Applications received in response to this announcement will be assigned for review and funding considerations according to established guidelines in the NIH Handbook for Referral.

In order to identify the response to this announcement, check "yes" and put **"The Biology of Neurodegenerative Disorders"** under item 2 on page 1 of the application. The original and five copies of the application should be mailed to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

An additional copy should be sent directly to the address below where further information may also be obtained:

Janett Trubatch, Ph.D.
Health Scientist Administrator
Demyelinating, Atrophic, and Dementing
Disorders Program
National Institute of Neurological and
Communicative Disorders and Stroke
Federal Building - Room 704
Bethesda, Maryland 20205

Telephone (301) 496-1431

NATIONAL SYMPOSIUM ON SCIENTIFIC AND PUBLIC ISSUES THAT ARISE FROM HEALTH RESEARCH INVOLVING VERTEBRATE ANIMALS

April 11-12, 1984

REGISTRATION FORM
(Please Type Or Print)

Name _____

Title/Organization _____

_____

Address _____

City/State/Zip _____

Telephone _____

Please forward no later than Friday, March 30, 1984. to:

Office for Protection from Research Risks
National Institutes of Health
Building 31 - Room 4B09
Bethesda, Maryland 20205

Telephone: (301) 496-7005

*U.S. GOVERNMENT PRINTING OFFICE : 1984 0-421-144/312

NIH Guide
for Grants and Contracts

Volume 13, No. 3, March 2, 1984

U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES

IN THIS ISSUE:

Continued

The NIH Guide is published at irregular intervals to announce scientific initiatives and to provide policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in grants and contracts activities administered by the National Institutes of Health.

Two types of supplements are published by the respective awarding units. Those printed on yellow paper concern contracts: solicitations of sources and announcement of availability of requests for proposals. Those printed on blue paper concern invitations for grant applications in well-defined scientific areas to accomplish specific program purposes.

Have You Moved?
If you present address differs from that shown on the address label, please send your new address to: Grants and Contract Guide Distribution Center, National Institutes of Health, Room B3BN10, Building 31, Bethesda, Maryland 20205, and attach your address label to your letter. Prompt notice of your change of address will prevent your name from being removed from our mailing list.

NOTICE

INDEX TO NIH GUIDE FOR GRANTS AND CONTRACTS

P.T. 04, 22, 34, 42, 44; K.W. 1200170, 1200180

The index to the NIH Guide for Grants and Contracts has been updated through December 1983. Approximately 1,500 copies will be mailed directly to the offices of sponsored research in all institutions currently receiving one or more National Institutes of Health (NIH) grants or contracts and to NIH staff who receive the Guide.

A limited number of copies are available for individuals who request them. To obtain a single copy please send a self-addressed mailing label to:

Office of Extramural Research and Training
National Institutes of Health
Building 1 - Room 111
Bethesda, Maryland 20205

NOTICE

NEW INSTITUTIONAL TRAINING GRANT

NONCOMPETING CONTINUATION APPLICATION FORM

P.T. 44; K.W. 1200170

The Division of Research Grants (DRG), National Institutes of Health (NIH), will convert to a new institutional training grants noncompeting continuation application form on or about March 1, 1984. The new training grant continuation form is identified by the form number PHS 6025-2 (1/83). It replaces the form numbered PHS 2499-2. DRG will continue to mail the forms directly to the program director of the grant. The forms will not be distributed through institutional control offices.

NOTICE

RECEIPT AND REFERRAL OF APPLICATIONS

P.T. 04, 22, 34, 42, 44; K.W. 1200170, 1200180

DIVISION OF RESEARCH GRANTS

The Division of Research Grants (DRG) is the central receipt point for all research grant and cooperative agreement applications submitted for consideration by the Public Health Service (PHS). More than 25,000 competitive applications annually are processed and assigned to review committees and to awarding organizations by the Referral Section. The following information is provided with the hope of reducing the time and effort of both applicants and NIH staff in the handling of research applications.

1. Waiver of Receipt Dates

   - The Referral Section considers requests for waivers only after the application has been received by the DRG.
   - A request for a waiver should be made in a covering letter submitted with the application. The letter should describe the extenuating circumstances that would justify special treatment.
   - Requests for waiver of a specified receipt date can be considered only after those applications which have arrived by the announced receipt dates have been processed. The regular receipt dates are specified in the grant application kit. Special or one-time dates are identified in the published announcement.

2. Unacceptable Applications

   Unacceptable applications include those that are:

   - Not appropriately signed by an authorized official of the applicant institution and the principal investigator.
   - Not sufficiently relevant to the research programs of the PHS.
   - Not prepared in accordance with instructions in terms of page limitations, human subject certification, number of copies, typing with black ribbon, etc.
   - Not revised in accordance with the instructions in the application kit when resubmitted following a previous review.
   - Lacking sufficient information to permit reviewers to make an assessment of technical merit.
   - Supplemental requests to applications not yet funded.

3. Communications from Principal Investigators Prior to Assignment

- Investigators who wish to provide information to facilitate the assignment and review of their applications should do so by including a covering letter with their application at the time of submission. This will assure consideration of the communication at the time of assignment and the effective use of NIH staff and consultants.

- Although Referral staff will consider requests for specific assignments for review, the final decision on assignment is made by staff based upon a number of factors. Among these are the subject matter of the application, potential conflicts of interest, timing relative to meeting date, history of the application, availability of review resources, and assigned review responsibilities of the committees as they relate to the content of the application.

- Pre-assignment communications should be addressed to:

  Chief of the Referral Section
  Referral and Review Branch
  Division of Research Grants
  National Institutes of Health
  Bethesda, Maryland 20205

4. Post-Assignment Communications

- Post-assignment communications prior to the review by the study section, should be addressed to the Executive Secretary identified on the "notification of assignment card" which is mailed to the applicant. Communications following review should be addressed to the Program Director of the awarding organization.

NOTICE

WORKSHOP ON HUMANS AS RESEARCH SUBJECTS: ISSUES AND CONCERNS FACING REVIEW BOARDS AND RESEARCH INVESTIGATORS

P.T. 42; K.W. 0701028, 1200270

A one and one-half day program on March 15-16, 1984, jointly sponsored by the National Institutes of Health, (NIH), Food and Drug Administration (FDA), and The University of Oklahoma Health Sciences Center will be held at the following location:

Center for Continuing Education
Fifth Floor - Nicholson Tower
Oklahoma Children's Memorial Hospital
940 NE 13th Street
Oklahoma City, Oklahoma 73104

The meeting will convene at 1:00 p.m. on March 15, with a plenary session overview of the responsibilities for protection of human subjects in research. On March 16, the program will continue until 5:00 p.m.

This regional conference on humans as research subjects will provide technical assistance to institutions, their staffs, research and clinical investigators, and members of their institutional review boards by identifying and clarifying their respective roles and responsibilities.

For further information, call or write:

Office of Research Administration
University of Oklahoma Health Science Center
P.O. Box 26901/L1B-115,
Oklahoma City, Oklahoma 73190

Telephone: (405) 271-2090

NIH/FDA also have planned regional workshops in other parts of the United States. For further information regarding these workshops contact:

Ms. Roberta Garfinkle
Education Program Coordinator
Office for Protection from Research Risks
Building 31 - Room 4B09
National Institutes of Health
Bethesda, Maryland 20205

NOTICE

CANCER CONTROL SCIENCE PROGRAM

P.T. 34; K.W. 1002014, 0701042

NATIONAL CANCER INSTITUTE

The Division of Cancer Prevention and Control (DCPC) of the National Cancer Institute (NCI) announces the conversion of its previous Request for Applications (RFA) entitled "Cancer Control Science Program: Program Projects" (NIH Guide for Grants and Contracts), Vol. 12, No. 9, September 23, 1983) into a traditional investigator initiated program project grant mechanism. No future RFA's for CCSP grants are anticipated. Under the NCI Program Project mechanism, applicants are requested to submit a letter of intent four to six months in advance of the regular due date for application (June 1, October 1, February 1).

Interested investigators should obtain copies of the 1983 "Guidelines for Cancer Control: Areas of Programmatic Interest" from:

Chief, Cancer Control Applications Branch
Division of Cancer Prevention and Control
National Cancer Institute
Blair Building - Room 1A07
9000 Rockville Pike
Bethesda, Maryland 20205

The 1983 "Guidelines for the Program Project Grant of the NCI" can be obtained from:

Referral Officer
Grants Review Branch
Division of Extramural Activities
National Cancer Institute
2115 E. Jefferson Street - Room 401
Rockville, Maryland 20852

NOTICE

WITHDRAWAL OF PROGRAM ANNOUNCEMENTS - SMOKING, TOBACCO AND CANCER PROGRAM

NATIONAL CANCER INSTITUTE

The National Cancer Institute (NCI) hereby withdraws its program announcements entitled "Smokeless Tobacco and Non-Tobacco Smoking Product Use: Identification of Initiation Mechanisms in Children and Adolescents" and "Tobacco and the Blue Collar Worker," which appeared in the NIH Guide for Grants and Contracts, Vol. 11, No. 14, December 31, 1982. Please contact the NCI Smoking, Tobacco, and Cancer Program (Dr. Thomas Glynn, (301) 427-8735) if there are any questions concerning these announcements.

ANNOUNCEMENT

REQUEST FOR COOPERATIVE AGREEMENT APPLICATIONS: RFA 84-HD-03

DATA COORDINATING CENTER FOR COOPERATIVE CLINICAL COMPARISON OF CHORION VILLUS SAMPLING AND AMNIOCENTESIS

P.T. 34; K.W. 1200280, 1200370, 1010013

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Application Receipt Date: April 30, 1984

The National Institute of Child Health and Human Development (NICHD) invites applications from organizations to serve as the Data Coordinating Center in a multicenter cooperative clinical study comparing the safety and accuracy of chorion villus sampling (CVS) with amniocentesis. Clinical centers to participate in this study were previously sought under RFA 84-HD-01.

This clinical study is planned to consist of four sequential phases in which the experience and results from each phase will determine whether or not, and in what manner, the next phase will be undertaken. Phasing of this study is envisioned as follows:

Phase I. Development of a protocol by consensus among the participating centers, preparation of an operations manual, and training of personnel (6 months).

Phase II. Initiation of the project in participating centers.

Phase III. a) Recruitment of additional centers and completion of enrollment (28 months).

b) Follow-up of enrolled patients (8 months).

Phase IV. Data analysis and reporting (12 months).

Applicants for the Data Coordinating Center award should provide an outline of their perception of the clinical study and an in-depth description of their plans and capabilities for data handling and analysis.

The mechanism of support for this Data Coordinating Center will be a cooperative agreement. Additional information and copies of a more detailed RFA which outlines the data coordinating center requirements for participation in the proposed study and the method for applying should be obtained from:

George G. Rhoads, M.D., M.P.H.
Chief, Epidemiology Branch
Epidemiology and Biometry Research Program
National Institute of Child Health
and Human Development
National Institutes of Health
Landow Building - Room 8A04
Bethesda, Maryland 20205

Telephone: (301) 496-1711

The deadline for receipt of applications by the NIH Division of Research Grants is April 30, 1984. Logistics and managerial practicality dictate that only applicant institutions in the United States are eligible.

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR COOPERATIVE AGREEMENT APPLICATIONS: RFA 84-AGDN-01

CLINICAL TRIALS OF BEHAVIORAL THERAPIES FOR URINARY INCONTINENCE IN THE ELDERLY

P.T. 34; K.W. 1200080, 1200280, 1200120, 1200890, 1201340, 0404002, 0701039

NATIONAL INSTITUTE ON AGING

DIVISION OF NURSING
BUREAU OF HEALTH PROFESSIONS
HEALTH RESOURCES SERVICES ADMINISTRATION

Application Receipt Date: May 20, 1984

The National Institute on Aging (NIA) and the Division of Nursing (DN) announce the availability of funds to support clinical trials of behavioral therapies for urinary incontinence in the elderly, beginning in fiscal year 1984. Behavioral interventions to be tested may include, but are not limited to: "bladder training" or "habit retraining", pelvic floor exercises, "contingency management", "shaping", and biofeedback approaches. Combinations of these techniques are also appropriate. Pharmacologic, surgical, and/or environmental interventions may be used in addition to "control" regimens for additional comparisons. Subjects for behavioral training may include elderly incontinent subjects and/or their care providers (e.g., nursing home staff). Female incontinent subjects should be over 55 years old; male incontinent subjects should be than 65 years old.

The proposed trials may include an initial "feasibility" phase to validate the operability of the applicants' recruitment techniques, treatment protocol, and other organizational variables, before proceeding to a full-scale trial. However, all proposed projects must include a "full-scale" trial; applications for feasibility studies alone will be considered to be nonresponsive.

The administrative and funding mechanism to be used to support these clinical trials will be a cooperative agreement between each of the awardees and NIA/DN. The major difference between a cooperative agreement and a research grant is that there will be substantial programmatic involvement of NIA and DN staff above and beyond the levels regularly required for traditional program management of grants. Under the terms of the cooperative agreement, the awardee defines the details of the project within the guidelines of the RFA, retains primary responsibility for performance of the activity, and agrees to accept close coordination, and participation of NIA/DN staff in all aspects of the scientific and technical management of the project in accordance with terms formally negotiated and mutually agreed upon prior to the award.

I. ELIGIBILITY

Eligibility is restricted to U.S. institutions; there are no other restrictions other than those specified in Public Health Service (PHS) policy. Because adequate

conduct of these trials will generally require a combination of expertise in behavioral sciences, nursing, geriatrics, and urodynamics, proposed projects should generally include personnel with expertise in all these fields. The adequacy of expertise in these fields will be used as a criterion for review of applications.

II. LENGTH OF SUPPORT

The duration of proposed projects may be up to five years. Funding beyond the first year will be contingent on satisfactory progress and availability of funds. Renewal applications may be submitted, but no funds have been specifically reserved for renewals at this time.

III. START DATE AND FINANCING

The start date for funded projects will be approximately September 30, 1984. A total of up to $800,000 ($400,000 by NIA and $400,000 by the Division of Nursing) will be allocated to fund the initial year's awards. The number of awards will depend on the quality and research scope of approved applications.

The deadline for receipt of applications will be May 20, 1984. Prospective applicants should obtain a copy of the RFA before applying. The RFA and additional information are available from:

Evan Hadley, M.D.
Geriatrics Branch, BRCM
National Institute on Aging
Nation Institutes of Health
Building 31 - Room 5C-21
Bethesda, Maryland 20205

Telephone: (301) 496-1033

Doris Bloch, Dr. P.H., R.N.
Chief, Research Support Section, NRAB
Division of Nursing, BHPr
Health Resources and Services Administration
Parklawn Building - Room 5C-09
Rockville, Maryland 20857

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA 84-CA-05

SMOKING PREVENTION AND CESSATION AMONG BLACK POPULATIONS

P.T. 34; K.W. 0404019, 0701042, 1200540

NATIONAL CANCER INSTITUTE

Application Receipt Date: June 15, 1984
Letter of Intent Receipt Date: May 15, 1984

The Smoking, Tobacco, and Cancer Program (STCP), National Cancer Institute (NCI) is interested in supporting studies to determine the long-term effect of interventions designed to prevent the onset and/or reduce the prevalence of cigarette smoking among U.S. Black populations.

The proposed studies should seek to: (1) develop and evaluate innovative intervention strategies to prevent or reduce cigarette smoking among U.S. Black populations and (2) develop and evaluate assessment procedures for determining the long-term effectiveness of smoking interventions among U.S. Black populations.

I. PROGRAM OBJECTIVES AND SCOPE

The purpose of this RFA is to solicit applications from qualified investigators interested in developing innovative intervention programs focused on U.S. Black populations and determining the long- term effectiveness of these programs on the prevention and cessation of habitual cigarette smoking among Blacks, especially high risk Black groups (e.g., adolescents, low-income).

The focus of the studies envisioned thus must be on the long-term effectiveness of interventions aimed at Black populations. It is anticipated, in keeping with the goals of the NCI Cancer Control Program, that studies funded under this RFA will be Phase III (i.e., for the purposes of this RFA, controlled studies of cancer control interventions in sizeable groups which may not, however, be representative of the larger population) and Phase IV (i.e., interventions designed and carried out with a sample of the population in such a way that the results obtained are representative of results in large target populations) investigations. It is recognized, however, that there are substantial gaps in our knowledge concerning smoking among Blacks and, in particular, knowledge that may be essential to the development of an effective and durable intervention program. Therefore, where necessary and specifically justified in the application, highly controlled studies of the acquisition process, epidemiological issues, or other related research questions which could influence the effectiveness of prevention/cessation efforts may be addressed in the

intervention studies. These research questions should not, however, become the overriding interest of the study, but rather be integrated as complementary adjuncts to the interventions.

The objective of these studies is to develop and evaluate the effectiveness of innovative intervention strategies to prevent or reduce cigarette smoking among U.S. Black populations. No restrictions are placed on the type of interventions (e.g., media-based, self-help, commercial methods), subgroups that may be studied (e.g., adolescents, females, low-income groups), or intervention sites (e.g., schools, physician's office, community-wide).

Prospective investigators should note (1) that the outcome measure of these studies should be incidence of smoking behavior, not cancer incidence; and (2) that the desired overall outcome of studies event ually supported through this RFA are interventions that are a) cost-beneficial; b) cost-effective; c) durable in their effects; d) generalizable; and e) readily adoptable by others with only minor modifications and little or no external economic or technical aid.

II. ELIGIBILITY REQUIREMENTS

Grants may be awarded to profit and nonprofit organizations and institutions, governments and their agencies, and occasionally to individuals. All applications received in response to this RFA will be reviewed by an appropriate NIH Initial Review Group. Assignments for possible funding will be governed by the usual referral guidelines.

III. MECHANISM OF SUPPORT

This RFA will use the NIH grant-in-aid. Responsibility for the planning, direction, and execution of the proposed research will be solely that of the applicant. The total project period for applications submitted in response to the present RFA should not exceed five years.

IV. ANTICIPATED NUMBER OF AWARDS

The intent is to fund up to five projects, with total costs for all projects amounting to approximately $1.5 million for the first year.

V. LETTER OF INTENT AND APPLICATION RECEIPT DATE

Prospective applicants are asked to submit a one-page letter of intent, including a brief synopsis of proposed areas of research and identification of any other participating institutions, to Dr. Thomas J. Glynn (see address in Section VI) by May 15, 1984.

Applications prepared on Form PHS 398 should be received by the Division of Research Grants, NIH, by June 15, 1984 to ensure their review.

VI. REQUESTS FOR COPIES OF RFA AND INFORMATION

To obtain a copy and/or other information, please contact:

Thomas J. Glynn, Ph.D.
Program Director for Smoking Research
Office of the Director, DCPC
National Cancer Institute
National Institutes of Health
Blair Building - Room 101
9000 Rockville Pike
Bethesda, Maryland 20205

Telephone: (301) 427-8735

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA 84-CA-06

SMOKING PREVENTION AND CESSATION AMONG HISPANIC POPULATIONS

P.T. 34; K.W. 0404019, 0701042, 1200540

NATIONAL CANCER INSTITUTE

Application Receipt Date: June 15, 1984
Letter of Intent Receipt Date: May 15, 1984

The Smoking, Tobacco, and Cancer Program (STCP), National Cancer Institute is interested in supporting studies to determine the long-term effect of interventions designed to prevent the onset and/or reduce the prevalence of cigarette smoking among U.S. Hispanic populations.

The proposed studies should seek to: (1) develop and evaluate innovative intervention strategies to prevent or reduce cigarette smoking among U.S. Hispanic populations and (2) develop and evaluate assessment procedures for determining the long-term effectiveness of smoking interventions among U.S. Hispanic populations.

I. PROGRAM OBJECTIVES AND SCOPE

The purpose of this RFA is to solicit applications from qualified investigators interested in developing and evaluating innovative intervention programs focused on U.S. Hispanic populations and determining the long-term effectiveness of these programs on the prevention and cessation of habitual cigarette smoking among Hispanics.

The focus of the studies envisioned thus must be on the long-term effectiveness of interventions aimed at Hispanic populations (including, e.g., sub-populations such as Mexican-Americans and Puerto Ricans and high-risk Hispanic groups such as adult males and adolescents). It is anticipated, in keeping with the goals of the NCI Cancer Control Program, that studies funded under this RFA will be Phase III (i.e., for the purposes of this RFA, controlled studies of cancer control interventions in sizeable groups which may not, however, be representative of the larger population) and Phase IV (i.e., interventions designed and carried out with a large, distinct, and well-characterized population or a sizeable sample of the population in such a way that the results obtained are representative of results in large target populations) investigations. It is recognized, however, that there are substantial gaps in our knowledge concerning smoking among Hispanics and, in particular, knowledge that may be essential to the development of an effective and durable intervention program. Therefore, where necessary and specifically justified in the application,

highly controlled studies of the acquisition process, epidemiological issues, or other related research questions which could influence the effectiveness of prevention/cessation efforts may be addressed in the intervention studies. These research questions should not, however, become the overriding interest of the study, but rather be integrated as complementary adjuncts to the interventions.
The objective of these studies is to develop and evaluate the effectiveness of innovative intervention strategies to prevent or reduce cigarette smoking among U.S. Hispanic populations. No restrictions are placed on the type of interventions (e.g., mediabased self-help, commercial methods), subgroups that may be studied (e.g., adolescents, females, low-income groups), or intervention sites (e.g., schools, physician's office, community-wide).

Prospective investigators should note (1) that the outcome measure of these studies should be incidence of smoking behavior, not cancer incidence; and (2) that the desired overall outcome of studies eventually supported through this RFA are interventions that are a) cost-beneficial; b) cost-effective; c) durable in their effects; d) generalizable; and e) readily adoptable by others with only minor modifications and little or no external economic or technical aid.

II. ELIGIBILITY REQUIREMENTS

Grants may be awarded to profit and nonprofit organizations and institutions, governments and their agencies, and occasionally to individuals. All applications received in response to this RFA will be reviewed by an appropriate NIH Initial Review Group. Assignments for possible funding will be governed by the usual referral guidelines.

III. MECHANISM OF SUPPORT

This RFA will use the NIH grant-in-aid. Responsibility for the planning, direction, and execution of the proposed research will be solely that of the applicant. The total project period for applications submitted in response to the present RFA should not exceed five years.

IV. ANTICIPATED NUMBER OF AWARDS

The intent is to fund up to five projects, with total costs for all projects amounting to approximately $1.5 million for the first year.

V. LETTER OF INTENT AND APPLICATION RECEIPT DATE

Prospective applicants are asked to submit a one-page letter of intent, including a very brief synopsis of proposed areas of research and identification of any other participating institutions, to Dr. Thomas J. Glynn (see address in Section VI) by May 15, 1984.

Applications prepared on Form PHS 398 should be received by the Division of Research Grants, NIH, by June 15, 1984 to ensure their review.

VI. REQUESTS FOR COPIES OF RFAs AND INFORMATION.

To obtain a copy and/or for further information, please contact:

Thomas J. Glynn, Ph.D.
Program Director for Smoking Research
Office of the Director, DCPC
National Cancer Institute
National Institutes of Health
Blair Building - Room 101
9000 Rockville Pike
Bethesda, Maryland 20205

Telephone: (301) 427-8735

ANNOUNCEMENT

REQUEST FOR APPLICATIONS: RFA

84-AM-03

PRESERVATION OF THE DONOR LIVER AND ASSESSMENT OF FUNCTION

P.T. 34; K.W. 1201300, 1200400, 0603000

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Application Receipt Date: July 16, 1984

I. BACKGROUND INFORMATION

The number of institutions now performing liver transplantation and the number of liver transplants being performed is increasing. A Consensus Conference on Liver Transplantation held at the National Institutes of Health on June 20-23, 1983, concluded that "liver transplantation is a therapeutic modality for end-stage liver disease that deserves broader application".* The need for donor livers may prove to be a limiting factor in transplantation, especially the need for livers in children. The availability of patients receiving transplants offers an important new resource for research into a variety of important questions, some of which were addressed in a multi-institute announcement in the NIH Guide, January 1984. Improved methods of preserving donor livers and of assessing the adequacy of their function prior to transplantation could make a major difference in the number of livers available for necessary transplants.

Many cadaveric liver donors are individuals who have been involved in automobile accidents, sustained closed head injuries, and have been maintained on respirators. Frequently they have had a period of hypoxemia and/or hypotension at the time of their injury or during some point in their resuscitation. The effect of a short period of hypoxemia and/or hypotension on donor liver tissue is unknown. A prolonged time of hypoxemia (i.e. four hours) causes massive and irreversible liver damage. As a consequence such donors are no longer used.

*Digestive Diseases Advisory Board Report of 1983 - copies available from National Digestive Diseases Advisory Board, NIH Liver Consensus Conference of June 20-23, 1983 - copies available from Office of Medical Applications of Research, NIH

The programs are described in the Catalog of Federal Domestic Assistance (CFDA) No. 13.848, Digestive Diseases and Nutrition. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42CFR Part 52 and CFR Part 74. This program is not subject to Health Systems Agency review.

Currently the liver from the donor is flushed initially with heparinized Ringers solution. It is then flushed with Collins solution or a plasma protein fraction and put on ice for preservation and transportation. This preservation is effective for up to 8-10 hours without apparent harm to the liver and facilitates utilizing donors from one part of the country for suitable recipients in another part of the country.

II. RESEARCH GOALS AND SCOPE

The specific goal of this announcement is to encourage investigators with interest and expertise in the area of organ preservation to submit research grant applications in the area of liver research. The following areas of research are provided as examples only and are not meant to restrict applicants from submitting other applications germane to the topic of liver preservation and assessment of liver function.

- With renal grafts, methods of pulsative perfusion has given preservation of these organs up to 72 hours. These techniques have not been successfully applied to liver preservation. Liver preservation by cold storage is currently limited to 10 hours. A longer preservation time could allow time for tissue typing and matching, transportation over longer distances, and more testing of the functioning capacity of the liver. Better cold storage solutions or a machine providing pulsatile perfusion or other means of prolonging viability should be developed for liver storage. Potential pharmacologic stabilization of the organ may be a feasible approach.

- It is frequently difficult to determine the viability of the liver and the extent to which exposure to either hypoxia or hypotension has altered the function of the donor liver. Currently, the decision to use pressure of the patient and (b) biochemical tests such as SGOT, SGPT, alkaline phosphatase and bilirubin. Specific enzyme systems in the liver which predict organ viability and reliable liver function tests, are examples of approaches that may be testable.

- The degree of damage in potential donor livers which is still compatible with recovery of normal liver function and successful liver transplantation is unknown. Such information could greatly increase the availability of donor livers.

III. MECHANISM OF SUPPORT

The mechanism of support for this program will be the grant-in-aid: Research Project Grants (R01), New Investigator Research Grants (R23), and Program Project Grants (P01). It is anticipated that five awards will be made, dependent on the receipt of a sufficient number of applications of high scientific merit and contingent upon receipt of appropriated funds for fiscal year 1985. The earliest funding would be April 1985. All policies and requirements that normally govern the grant programs of the PHS apply. All applicants, both non-profit and for-profit institutions are eligible. This is a one time invitation.

IV. REVIEW PROCEDURES AND CRITERIA

A. Review Procedure

Applications received in response to this announcement will be reviewed for responsiveness by NIH staff. Those applications considered to be responsive will be reviewed for scientific and technical merit by an initial review group which will be convened by the Division of Research Grants, NIH, solely to review these applications. The secondary review for relevance and responsiveness to the RFA will be made by the National Arthritis, Diabetes and Digestive and Kidney Diseases Advisory Council.

Applications considered unresponsive will be either returned or considered with other unsolicited grant applications received during that NIH review cycle, at the applicant's option.

B. Review Criteria

The factors considered to be important for review include a demonstrated knowledge of the applicable science, adequacy of facilities and commitment, availability of research material, and in-depth knowledge of the state-of-the-art to which the announcement is directed. The application will be judged upon the overall scientific merit, adequacy of methodology, facilities and resources, commitment of time and cost effectiveness of the proposal.

V. METHOD OF APPLYING

Applications should be submitted on form PHS 398, the application for the traditional research grant. Application kits containing this form and the necessary instructions are available in most institutional business offices or from the Division of Research Grants (DRG), NIH. The title **"PRESERVATION OF THE DONOR LIVER, NIADDK, and RFA Number 84-AM-03"** should be typed in Section 2 of the first page of the application. Applications must be sent to the following:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
5333 Westbard Avenue
Bethesda, Maryland 20205

RECEIPT AND REVIEW SCHEDULE

Receipt Date	Initial Review Group	Council Meeting	Earliest Possible Start Date
New			
July 16, 1984	October, 1984	Jan/Feb, 1985	April 1, 1985

VI. IDENTIFICATION OF CONTACT POINT

Sarah C. Kalser, Ph.D.
Liver and Biliary Diseases Program
National Institute of Arthritis, Diabetes
and Digestive and Kidney Diseases

Telephone: (301) 496-7858

ANNOUNCEMENT

1985 WHO FELLOWSHIPS FOR TRAVEL/STUDY ABROAD

P.T. 22, 48; K.W. 0701015, 0701018, 0701043, 0701026

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Application Receipt Date: September 30, 1984

The World Health Organization (WHO) will make available in 1985 a limited number of short-term fellowships for travel/study abroad related to the improvement and strengthening of health services in the United States. This support is limited to United States citizens engaged in operational or educational aspects of health, allied health, environmental health and engineering activities employed by state or local governments or educational agencies. Federal employees are not eligible to apply.

A selection committee of health professionals will recommend the awarding of fellowships based on the applicant's professional background; need, objectives and locale of travel; and the utilization of the experience upon return to the United States. Applications will not be considered for such as basic research, attendance at international meetings nor from undergraduate or graduate students. Medical interns and residents are considered to be in graduate training.

The fellowship award will include per diem and transportation. Employers of successful applicants are expected to endorse the application and continue the applicant's salary through the fellowship period. Except in unusual circumstances, the fellowships will be limited to short-term programs of one to two months. The number of fellowships awarded will be governed by the amount of funds available. Deadline for the submission of the application is September 30, 1984.

Additional information and application forms may be obtained from the following:

Secretary
WHO Fellowships Selection Committee
Health Resources and Services Administration
Parklawn Building - Room 16A-17
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: 301 - 443-6580

ANNOUNCEMENT

BIOMEDICAL RESEARCH FELLOWSHIP OPPORTUNITIES ABROAD

P.T. 22, 48; K.W. 1200180, 0104000

JOHN E. FOGARTY INTERNATIONAL CENTER FOR ADVANCED STUDY IN THE HEALTH SCIENCES

The John E. Fogarty International Center for Advanced Study in the Health Sciences (FIC) of the National Institutes of Health announces the availability of postdoctoral fellowships to U.S. health scientists who wish to conduct collaborative research abroad. The purpose of these fellowships is to enhance the exchange of research experience and information in the biomedical, behavioral and health sciences.

Programs Available to U.S. Citizens or Permanent U.S. Residents:

ALEXANDER VON HUMBOLDT FOUNDATION POSTDOCTORAL RESEARCH FELLOWSHIPS
(Supported by the Federal Republic of Germany)

FRENCH NATIONAL INSTITUTE OF HEALTH AND MEDICAL RESEARCH POSTDOCTORAL FELLOWSHIPS
(Supported by the Government of France)

NIH-FRENCH NATIONAL CENTER FOR SCIENTIFIC RESEARCH EXCHANGE PROGRAM
(Jointly Supported by the Governments of France and the United States)

IRISH MEDICAL RESEARCH COUNCIL POSTDOCTORAL FELLOWSHIP
(Supported by the Government of Ireland)

SENIOR INTERNATIONAL FELLOWSHIPS
(Supported and administered by the FIC)

SWEDISH MEDICAL RESEARCH COUNCIL FELLOWSHIPS
(Supported by the Government of Sweden)

SWISS NATIONAL SCIENCE FOUNDATION POSTDOCTORAL FELLOWSHIPS
(Supported by the Government of Switzerland)

The eligibility requirements of each program vary and this information is provided in each program's brochure which is available upon request. However, at a minimum, each candidate must have an earned doctoral degree in one of the behavioral, biomedical or health sciences and some postdoctoral experience.

The receipt date for applications to the FIC Senior International Fellowship Program is June 1, 1984. The receipt date for all other applications except those to the Alexander von Humboldt Foundation is October 1, 1984. Applications for the Alexander von Humboldt Foundation Postdoctoral Research Fellowships are available and are accepted throughout the year. For those fellowship programs with an October 1 receipt date,

application kits will be available from April 1, 1984 to September 15, 1984. The organization that provides financial support for each of the programs selects candidates for participation. While the maximum period of support for all programs is one year, the minimum period of support varies with each program.

Prospective applicants for Senior International Fellowships, the FIC sponsored program, may obtain information brochures from the address listed below. However, application kits for Senior International Fellowships may be requested only through the applicant's dean or equivalent institutional official any time between January 15 and May 15, 1984.

All correspondence should refer clearly to the specific program of interest. For further information, please send a self-addressed label with your request to:

International Research and Awards Branch
Fogarty International Center
National Institutes of Health
Bethesda, Maryland 20205

ANNOUNCEMENT

RESEARCH ON ANORECTAL DISEASES AND DISORDERS

P.T. 34, 42, 44, 22; K.W. 1200400, 1200480, 1200410, 0404000, 0404002

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISEASES

NATIONAL INSTITUTE ON AGING

The National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK) and the National Institute on Aging (NIA) announce a continuing interest in basic and clinical research and research training in anorectal diseases and disorders.

I. BACKGROUND

The diseases and disorders represented in this announcement include hemorrhoids, fissures, fistulas, rectal prolapse, constipation, anorectal pain, fecal incontinence, and congenital anomalies. Also included are those basic studies of anorectal structure and function, and relationship of the anorectum to the more proximal digestive tract, which are required for understanding of anorectal diseases and disorders and for understanding the relationship of the anorectum to gastrointestinal normal and abnormal functions and general health.

There is a marked ignorance of anorectal diseases and disorders on the part of the public, the general physician, and the biomedical research community. In fact, anorectal diseases and disorders represent a major national problem in terms of morbidity and detraction from the quality of life. For example, for treatment of hemorrhoids alone, there are over 2.5 million patient-physician visits per year resulting in about 240,000 hemorrhoidectomies requiring hospitalization.[1] Data on hemorrhoids, as with other anorectal disorders, are not current. In 1982, the prevalence of hemorrhoids was about 10 million and the annual incidence about 1 million in the U.S.[2] These figures have probably continued upward with increases in population, especially among adults. The magnitude of morbidity and compromise of the quality of life is similar for other anorectal problems such as fecal incontinence. Fecal incontinence is encountered in all age groups as a significant problem, and emerges as a problem of major proportions for the elderly. Congenital anorectal anomalies are frequently life-threatening for the neonate, and commonly leave the young patient with a lifetime of disfiguring and disabling problems.

This program is described in the Catalog of Federal Domestic Assistance No. 13.848, Digestive Diseases and Nutrition and No. 13.866, Aging Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74; and Section 472, 42 USC 289L-1 administered under PHS grant policies and Federal Regulations 42 CFR Part 66. This program is not subject to Health Systems Agency review.

In contrast to the national significance of anorectal health problems, this field has always been markedly underrepresented in biomedical research. There has been a dearth of applications to NIH that address these problems, and therefore there are neither research nor research training grants supported by NIH in this area. The types of knowledge sought to address anorectal diseases and disorders are very broad and must be pursued through all major categories of biomedical research. For example:

A. Epidemiologic data on anorectal diseases and disorders are limited and should be developed to enable better understanding of the magnitude of anorectal problems, populations at particular risk, and as a guide to research on prevention, early diagnosis, and treatment.

B. Physiological data on normal and abnormal functions of the anorectal area are sparse. The functional anatomy of the region, its neural control, the role of neuropeptides, the role of nutrition, and the integration of the anorectal area with other levels of the gastrointestinal tract are all in need of further exploration.

C. Diagnostic and pathophysiological criteria for some anorectal diseases and disorders are inadequate. It is not uncommon, for example, that problems attributed to hemorrhoids frequently are not due to hemorrhoids. A tendency for the public to attribute all anal problems to hemorrhoids leads to a likelihood of postponement of needed evaluation and opportunity for more effective treatment of other anorectal or colonic problems.

D. Preventive and therapeutic practices addressing anorectal problems vary widely in the medical community. Similarly, there is marked variability in the type of training experienced by physicians and other practitioners who treat persons with anorectal problems. Existing preventive measures require further testing, and the theoretical and experimental basis for prevention methods needs extensive exploration and development. Current treatments require testing for efficacy and cost-effectiveness.

E. The knowledge foundation in basic science for research on anorectal problems is seriously inadequate. Embryogenesis and development of the anorectum require study, as do subsequent changes associated with childhood and adult years. Animal models of human anorectal problems should be sought and studied. Mathematical and computer-simulated models should be developed. Behavioral aspects of etiology and treatment are of major importance and require extensive study.

F. The opportunities for anorectal research suggest a value in collaborative studies between basic and clinical scientists. Rigorous clinical data are needed on anorectal problems to clarify diagnostic criteria, achieve understanding of etiology, and determine the most suitable methods for prevention, early diagnosis, and treatment. The relationship of the anorectum to the more proximal gastrointestinal tract is largely unexplored, both in the expression of sequelae to proximal gastrointestinal problems and as the source of such problems.

G. The most recent published Federal advisory position on anorectal disorders is that of the National Commission on Digestive Diseases (NCDD)[3]: "Anorectal disorders... contribute a disproportionate share of chronic discomfort and

disability due to gastrointestinal disease. Yet little is known of the etiology of rectal disorders, and treatment is based on clinical experience rather than controlled trials." The NCDD Workgroup on Clinical Research and Digestive Disease Centers and Specialized Facilities recommended "...support for studies of the etiology of these undramatic but important anorectal disorders, and for clinical trials of medical and surgical therapies." The National Digestive Diseases Advisory Board has recently endorsed this NCDD expression of research need. This announcement is in response to these Commission and Board expressions of research needs, and to the recommendations of a June 1983 NIH advisory workshop, "Opportunities in Anorectal Research."

REFERENCES:

1. Crossland, S. G., G. W. Geelhoed and D. G. Guy. 1981. Evaluation of benefits of different nutritional pre- and post-operative management of hemorrhoidectomy patients. Am. J. Proc. Gastr. Col. Rect. Surg. 32(5): 8, 10-12, 14.

2. 1972. Prevalence of Chronic Circulatory Conditions. United States, 1972. Vital and Health Statistics. Series 10 Number 94. 55 pp.

3. 1978. Report to the Congress of the U. S. of the National Commission on Digestive Diseases. Reports of the Workgroups. Research. Volume 4, Part 2A. pp. 513-514.

II. OBJECTIVES AND SCOPE OF RESEARCH AND RESEARCH TRAINING

Applications for research and research training in all areas of anorectal disorders, diseases, and related basic structure and function exclusive of neoplastic and infectious diseases are encouraged through this announcement.

III. MECHANISMS OF SUPPORT

Types of research applications considered appropriate to this announcement include the traditional project grant (R01), the new investigator research award (R23), the conference grant (R13), and the program project (P01). Career development and research training applications appropriate to this announcement include the clinical investigator award (K08), the research career development award (K04), the individual postdoctoral fellowship award (F32), the institutional training grant (T32) and the individual physician scientist award (K11). Specific forms are required when submitting an application: for the R01, R13, R23, K11, and P01 use PHS 398; for the F32 use PHS 416-1; and for the T32 use PHS 6025-1.

The responsibility for the planning, direction, and execution of the proposed research and/or research training will be solely that of the applicant. Applications will be reviewed competitively with all other applications considered for funding by the awarding institute. This is not a one-time announcement, but rather is a statement of ongoing NIADDK and NIA interest in research and research training in anorectal diseases and disorders.

IV. REVIEW PROCEDURES AND CRITERIA

Applications will be referred to the most appropriate initial review group and to a

review group for scientific merit and significance of the project, scientific and/or training competence of the proposed principal investigator and supporting faculty (where appropriate) in relation to the type of application involved, feasibility of the project, and the supportive nature of the research environment.

V. METHOD OF APPLYING

Applicants are encouraged to advise one of the sponsoring institutes, NIADDK or NIA, of intent to submit an application, and to seek advice and instructions if considering application for conference grant, program project, clinical investigator award, institutional training grant, or physician scientist award.

Application receipt dates, advisory council reviews, and awards dates will be 3 times per year as represented in the application forms.

Application kits are available at most institution business offices, or may be obtained from:

Office of Grant Inquiries
Division of Research Grants
Westwood Building - Room 448
National Institutes of Health
Bethesda, Maryland 20205

For item number 2, on page one of the application form check "YES" and type the title of this program announcement, "Research on Anorectal Diseases and Disorders." The completed original and six (6) copies should be sent to:

Application Receipt Office
Division of Research Grants
Westwood Building - Room 240
National Institutes of Health
Bethesda, Maryland 20205

VI. INQUIRIES AND CORRESPONDENCE

Requests for information and letters of intent should be directed to one of the following offices:

For digestive diseases:

Donald G. Murphy, Ph.D.
Special Emphasis Areas Program Director
Westwood Building - Room 3A15
National Institute of Arthritis, Diabetes, and
Digestive and Kidney Diseases
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-7455

For aging and incontinence:

Evan C. Hadley, M. D.
Acting Chief, Geriatrics Branch
Biomedical Research and Clinical Medicine Program
National Institute on Aging
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-1033

ANNOUNCEMENT

OTOSCLEROSIS AND EARLY PROGRESSIVE DEAFNESS

P.T. 34; K.W. 1200550, 1200990, 1200270, 1200280

NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

Application Receipt Dates: July 1, November 1 March 1

The Communicative Disorders program (CDP) of the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) invites grant applications for the purpose of conducting studies on the many facets of otosclerosis, including but not limited to the associated progressive sensorineural deafness, and the efficacy of sodium fluoride treatment.

I. BACKGROUND INFORMATION

Otosclerosis is a well-documented cause of adolescent and adult-onset conductive hearing loss, secondary to a focus of pathology in the otic capsule. There is, moreover, evidence to suggest that otosclerotic involvement of the otic capsule can lead to cochlear damage and thus to sensorineural hearing loss. Histological studies have documented slow and irregularly progressive foci of disease in the otic capsule. Early resorption of bone may occur either along the wall of a vascular channel or on a broader front. The mechanisms by which demineralization and resorption occur are incompletely understood; however, the processes of resorption and deposition of bone appear to continue and slowly extend to surrounding bone. Hydrolytic enzymes thought to be released from the otosclerotic foci have been suggested as possible causes for the sensorineural component of the hearing loss in some otosclerotic patients. Cases of unexplained progressive deafness of early onset may be a part of this larger problem. Medical therapy with sodium fluoride has been suggested by some investigators to be beneficial in promoting maturation of existing otosclerotic foci, and thus may assist in preventing progressive sensorineural hearing loss due to cochlear involvement. The study of otosclerosis presents several problems including the lack of a good animal model, the dearth of information concerning the molecular biology of otosclerosis, the possible implications of an autoimmune reaction, and the minute quantities of bony tissue available for study.

This program is described in the Catalog of Federal Domestic Assistance No. 13.853, Clinical Research, NINCDS. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to Health Systems Agency Review.

II. GOALS AND SCOPE

It is the intent of the Institute that a potential investigator or groups of investigators design a scientifically meritorious study utilizing the attributes of the investigator's institution(s) and patient population(s). Investigators are encouraged to consult with and to establish collaborative arrangements within their own institution and/or in other institutions, particularly those conducting similar studies. In the design of an objective clinical trial, if one is planned, several requirements should be met, including but not limited to: (1) an operational definition of the disease in all its phases; (2) objective documentation of the disease (validity and reliability of observations); (3) appropriate statistical design; (4) documentation of control for other disorders or factors which may affect the natural course of the disease, (5) an operational definition of successful medical treatment.

This announcement is designed to offer support for innovative clinically-related otolaryngologic-audiologic research protocols with goals of diagnosis, prevention, treatment and successful remediation of otosclerosis and unexplained early progressive deafness.

III. METHOD OF APPLYING

A. Application Procedures

Detailed instructions for applying are included in the PHS 398 (Revised 5/82) Grant Application Kit. Your institution's business office or grants and contracts office should have the PHS 398 kits, or single copies may be requested by writing to:

Office of Grants Inquiries
Division of Research Grants
National Institutes of Health
Westwood Building - Room 449
5333 Westbard Avenue
Bethesda, Maryland 20205

Please type **"OTOSCLEROSIS AND EARLY PROGRESSIVE DEAFNESS"** in item 2 on the face page of the application.

B. Eligibility

For-profit and non-profit organizations or institutions in the U.S. are eligible to apply. It should be noted that NINCDS will not support more than one study in a given department or specialty unit. Applicants are urged to contact the Program Administrator prior to submission of the formal application.

C. The Application

The applicant should prepare a complete application on research grant application form PHS 398 (Revised 5/82). The NINCDS recommends that the applicant consult with the Program Administrator, Communicative Disorders Program, NINCDS who will provide guidance in relation to budgetary and administrative details.

IV. TIMETABLE FOR RECEIPT AND REVIEW OF APPLICATIONS

A. Receipt

The original and six (6) copies of the application must be sent directly to:

Application Receipt Office
Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
5333 Westbard Avenue
Bethesda, Maryland 20205

B. Review Schedule

Applicants should note that there is approximately a 10-month time period from receipt of an application to activation of an award.

V. REVIEW PROCEDURES AND CRITERIA

A. Review Procedures

Applications will be reviewed for scientific and technical merit by an NIH initial review group and for program relevance by the National Advisory Neurological and Communicative Disorders and Stroke Council.

VI. STAFF CONTACT

For further information, potential applicants may write or call:

J. Buckminster Ranney, Ph.D.
Deputy Director
Communicative Disorders Program
National Institute of Neurological
and Communicative Disorders and Stroke
Federal Building - Room 1C-11
Bethesda, Maryland 20205

Telephone: (301) 496-1804

*U.S. GOVERNMENT PRINTING OFFICE : 1984 0-421-144/314

NIH Guide
for Grants and Contracts

U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES

Vol. 13, No. 4, March 30, 1984

IN THIS ISSUE:

The NIH Guide is published at irregular intervals to announce scientific initiatives and to provide policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in grants and contracts activities administered by the National Institutes of Health.

Two types of supplements are published by the respective awarding units. Those printed on yellow paper concern contracts: solicitations of sources and announcement of availability of requests for proposals. Those printed on blue paper concern invitations for grant applications in well-defined scientific areas to accomplish specific program purposes.

Have You Moved?
If you present address differs from that shown on the address label, please send your new address to: Grants and Contract Guide Distribution Center, National Institutes of Health, Room B3BN10, Building 31, Bethesda, Maryland 20205, and attach your address label to your letter. Prompt notice of your change of address will prevent your name from being removed from our mailing list.

NOTICE

NIH POLICY RELATING TO REPORTING AND DISTRIBUTION OF UNIQUE BIOLOGICAL MATERIALS PRODUCED WITH NIH FUNDING

P.T. 36, 16; K.W. 1014002, 1016004, 1200140, 1200490, 1200570, 1200820, 1201190

Scientific and technological advances attributable to biomedical research frequently result in unique biological materials, of which some are patentable inventions. Some examples are: specialized and/or genetically defined cells, including normal and diseased human cells; monoclonal cell lines; hybridoma cell lines; microbial cells and products; viruses and viral products; and recombinant nucleic acid molecules. In accord with the policy of the Department of Health and Human Services (DHHS), the National Institutes of Health (NIH), takes the position that such products, when they are developed through the expenditure of NIH funds, should be made available to other research workers and the general public. While the circumstances may vary, the NIH offers the following guidelines concerning materials developed through its awards.

A. NIH Policy on Distribution of Newly Developed Materials

The practice of sharing research results, not only information but also the actual biological materials, has been a major strength of our nation's biomedical enterprise. The NIH recognizes that the vast majority of scientists currently make these newly developed materials readily available to other research workers. The purpose of this announcement is to emphasize the NIH policy that all unique biological materials developed with NIH funding be readily available to the scientific community after publication of the associated research findings or announcement at conferences. Restricted availability of these materials can impede the advancement of basic research and the delivery of medical care to the nation's sick.

In order to facilitate the availability of unique or novel biological materials developed with NIH funds, the investigator may distribute the materials through his/her own laboratory or institution, or submit them, if appropriate, to facilities such as the American Type Culture Collection or similar repositories. In some instances sharing of such material may be impractical, but these are expected to be only infrequent exceptions. Investigators are encouraged to consult the appropriate Health Scientist Administrator at NIH who may be of assistance in determining an appropriate distribution mechanism.

B. NIH Policy on Reporting of Newly Developed Materials

Investigators are reminded that unique or novel biological materials and their products are considered to be inventions and therefore are subject to the various laws and regulations applicable to patents. Accordingly, the NIH

requires that grantees and contractors adhere to grant regulations and contract clauses, respectively, pertaining to the reporting of inventions to the NIH. Only those cell lines or their products for which a demonstrated use exists or which have a potential for commercial development need be reported. However, when reporting is indicated, it should occur at the earliest possible time and should not await the end of the budget period or the expiration of the award. Examples of potentially reportable inventions in the areas of molecular and cell biology include synthesis of molecules with unique properties; special tests, assays or components (diagnostic tests); and cells or products of cells. Some investigators may wish to attempt to patent these materials; if so, the usual criteria for reporting and patenting inventions should be used. All not-for-profit institutions and small businesses should be aware that, as a consequence of Public Law 96-517 and OMB Circular A-124, they have first right to all inventions developed at their institutions with funds from the Federal Government.

For further information on the reporting of inventions and the filing of patent applications contact:

Messrs. Leroy B. Randall or Thomas G. Ferris
Patent Branch, Office of the General Counsel
Department of Health and Human Services
Westwood Building - Room 5A03
Bethesda, Maryland 20205

Other questions or comments on this issuance should be sent to:

Dr. Melvin S. Fish
Special Assistant to the Deputy Director
for Extramural Research and Training
National Institutes of Health
Building 1 - Room 109
Bethesda, Maryland 20205

NOTICE

INTERNATIONAL NUCLEIC ACID SEQUENCE COMPENDIUM AVAILABLE

P.T. 32; K.W. 1200920, 1201190, 1200490 1004008

Nucleotide Sequences 1984, the first international compendium of nucleic acid sequences, will be published as a supplement to the May 1984 issue of GenBank(tm), the Genetic Sequence Data Bank, and the European Molecular Biology Laboratory (EMBL) Nucleotide Sequence Data Library, contains information on over 4000 nucleic acid sequences, representing nearly 3 million base pairs. This includes virtually all sequences reported between 1967 and late 1983.

The compendium is organized into 10 categories, with sequences grouped by organism within each category. The categories are: mammalian sequences, other vertebrate sequences, invertebrate sequences, plant sequences, organelle sequences, bacterial sequences, structural RNA sequences, viral sequences, bacteriophage sequences, and synthetic and recombinant sequences. The publication also contains keyword phrases, taxonomic classification of the nucleic acid source, and author indexes, and lists where the entries appear in GenBank(tm) and the EMBL sequence library.

Entries are annotated to indicate the locations of coding regions and other sites of biological significance. Full bibliographic information and brief summaries of the points made about the sequences in the papers in which they were published are also included.

GenBank(tm) was established in 1982 as a computerized repository of all published nucleic acid sequences greater than 50 nucleotides in length. Data are collected, verified, and annotated at the Los Alamos National Laboratory. Bolt Beranek and Newman Inc., a research, development, and consulting firm in Cambridge, Massachusetts, handles the computerization and distribution of the information to scientists.

The GenBank(tm) database is also available for online use or as computer-readable magnetic tape. Future plans are to provide the data on floppy disks suitable for personal computers as well. For information on access and cost, contact the following:

Bolt Beranek and Newman Inc.
10 Moulton Street
Cambridge, Massachusetts 02238

Telephone: (617) 497-2742.

GenBank(tm) is coordinated by the National Institute of General Medical Sciences (NIGMS) National Institutes of Health (NIH), with cosponsorship by three other NIH components--the National Cancer Institute (NCI), National Institute of Allergy and Infectious Diseases (NIAID), and the Division of Research Resources (DRR)-- well as the National Science Foundation (NSF), Department of Energy (DOE), and the Department of Defense (DoD).

EMBL's sequence library was also created in 1982. It is an activity of the laboratory, which was established in 1974 in Heidelberg, Federal Republic of Germany (FRG), as a component of a treaty organization comprised of Austria, Denmark, the FRG, France, Israel, Italy, the Netherlands, Sweden, Switzerland, and the United Kingdom.
Future releases from GenBank(tm) and EMBL will contain listings from both databases.

To order a copy of the 2-volume set, send a check or money order for $75.00 to:

IRL Press
Suite 907
1911 Jefferson Davis Highway
Arlington, Virginia 22202

NOTICE

BREAST CANCER SERUM BANK

P.T. 36; K.W. 1200140, 1002014

NATIONAL CANCER INSTITUTE

A bank of serum specimens from women at varying risks of breast cancer has been established in the Diagnosis Branch, Division of Cancer Biology and Diagnosis (DCBD), National Cancer Institute (NCI). Panels of test specimens can be secured to evaluate newly discovered biological markers for breast cancer, to verify preliminary data and to study multiple markers for early detection of breast cancer. Sera are maintained at -70°C in 1 ml sealed glass vials.

Requestors for test panels must document the discriminatory power of their assays. The Bank cannot support feasibility studies based on theoretical considerations nor can it handle large population based epidemiological studies. The assays must not require more than 1 ml of serum for accurate determination. Requestors must agree to accept specimens under a blind code number and report the results to NCI. Some duplicates will be included in each test panel. To request a test panel it is sufficient to write a letter addressing above points to:

Dr. I.J. Masnyk
Division of Cancer Biology
and Diagnosis
National Cancer Institute
Building 31 - Room 3A04
Bethesda, Maryland 20205

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

84-CA-07

CANCER CONTROL SMALL GRANTS RESEARCH PROGRAM

P.T. 34; K.W. 1200270, 1200280, 0403004, 0413000, 1002014

NATIONAL CANCER INSTITUTE

Application Receipt Date: May 15, 1984

I. BACKGROUND INFORMATION

The Division of Cancer Prevention and Control (DCPC) of the National Cancer Institute (NCI) invites Small Grants Research applications from interested investigators. This program is designed to aid and facilitate the growth of a nationwide cohort of scientists with a high level of scientific research expertise in the field of cancer control. Its major objective is to encourage new investigators from a variety of academic disciplines to apply their skills to scientific research in the field of cancer control intervention research. The intent is to fund up to 10 awards with total costs for all projects not to exceed to $350,000. This level of activity is dependent on the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the NCI, the award of grants pursuant to this RFA is also contingent upon the continuing availabilty of funds for this purpose.

II. RESEARCH GOALS AND SCOPE

A Cancer Control Small Grants Research Award is designed to encourage scientists from a variety of academic disciplines to apply their skills to scientific investigations in the field of cancer control intervention research.

A. Definition of Cancer Control

Cancer control is defined as the reduction of cancer incidence, morbidity, and mortality through an orderly sequence from research on interventions and their impact in defined populations to the broad, systematic application of the research results.

This program is described in the Catalog of Federal Domestic Assistance, No. 13.399, Cancer Control. Grants are awarded under the authority of the Public Health Service Act, Section 301 (42 USC 241) and Section 403 (42 USC 284) and administered under PHS grant policies and Federal Regulations, most specifically at 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to review by a Health Systems Agency.

B. Phases of Cancer Control

Cancer control research studies are classified into one of five phases which represent the orderly progression noted in the above definition: (I) hypothesis development; (II) methods development and testing, (III) controlled intervention trials to establish cause and effect relationships; (IV) research in defined populations; and (V) demonstration and implementation studies. The Division is primarily interested in research on cancer control intervention in Phases II through V.

Copies of DCPC's Grant Guidelines for Cancer Control: Areas of Programmatic Interest which outlines specific areas of cancer control research interest, may be obtained from Dr. Robert G. Burnight, Program Director, 301-427-8788.

III. MECHANISMS OF SUPPORT

This RFA will use the NIH Grant-in-Aid. Responsibility for planning, direction, and execution of the proposed research will be solely that of the applicant. Except as otherwise stated below, awards will be administered under PHS grants policy as stated in the Public Health Service Grants Policy Statement, DHHS Publication No. (OASH) 82-50,000 Revised December 1, 1982.

Allowable direct costs include personnel, supplies, publication costs, travel, and equipment expenses, up to a maximum of $25,000. In general, total costs (direct and indirect) should not exceed $35,000. The duration of support is one year but may be longer (up to two years) if the funding limits noted above are not exceeded.

Grants may be awarded to profit and non-profit organizations and institutions, governments and their agencies, and occasionally to individuals. This type of solicitation (the RFA) is utilized when it is desired to encourage investigator-initiated research projects in areas of special importance to the National Cancer Program. Applicants funded under the RFA are supported through the customary National Institutes of Health (NIH) grant-in-aid in accordance with PHS policies applicable to Research Project Grants, including cost sharing. The receipt date for this RFA solicitation is May 15, 1984. It will be reissued, approximately annually.

IV. ELIGIBILITY

Investigators are eligible to apply for a small grant to support research on a cancer control topic if they have never received NCI cancer control funding and are interested in conducting exploratory studies in cancer control research.

Submission of an application under this announcement precludes concurrent submission of a regular research grant application containing the same research proposal. In addition, small grant research support may not be used to supplement research projects currently supported by Federal or non-Federal funds, or to provide interim support of projects under review by the Public Health Service (PHS).

V. REVIEW PROCEDURES AND CRITERIA

Responsive applications will be reviewed for scientific and technical merit by a committee consisting primarily of non-Federal technical and scientific experts and will be evaluated subject to the following criteria:

1. Quality of the principal investigator's education and/or scientific training, and potential for contribution as an investigator in the field of cancer control intervention research.

2. Evaluation of the research proposal for scientific merit, including (a) originality; (b) feasibility; (c) adequacy of design; (d) plans for analyses and evaluation of data; and (e) soundness of the research plan.

3. Adequacy of resources and the supportive nature of the research environment.

4. Appropriateness of the proposed budget.

5. Significance in relation to cancer control intervention research.

Unresponsive applications, i.e., those applications not meeting the criteria for cancer control intervention research, will be returned.

VI. METHOD OF APPLYING

The regular research grant application form PHS-398, (rev. 5/82) must be used in applying for these grants. These forms are available at most institutional business offices from the following:

Division of Research Grants
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland, 20205

or from the Program Director. **Cancer Control Small Grants Research, DCPC, NCI,** and the RFA number **84-CA-07** should be typed on line 2 of the face page of the application form.

You are requested to submit the application in a package clearly marked **CANCER CONTROL SMALL GRANTS RESEARCH PROGRAM, DCPC, NCI** on the outside.

1. This package should contain a signed, typewritten original of the application, including the Checklist, and six signed, exact photocopies, in one package to the following address:

Division of Research Grants
Westwood Building - Room 240
5333 Westbard Avenue
Bethesda, Maryland 20205.

The photocopies must be clear and single-sided. A preaddressed mailing label is provided in the application kit. Include the the self-addressed three-part postcard, form PHS-3830 provided in the application kit.

2. The following application receipt and review dates apply:

Application Receipt Date	Committee Review	Earliest Possible Funding Date
May 15	July	September

3. The following additional page limitations (typewritten, single-spaced) apply to sections of the PHS-398 application:

Biographical Sketch - do not exceed one page.

Section 2, Research Plan (page 15 of instructions).

Specific Aims and Significance - one page each.

Progress Report and Preliminary Studies - if applicable, two pages.

Experimental Design and Methods - ten pages.

Human Subjects and Literature Cited - two pages each.

These page limitations and others in the PHS-398 Application Instructions must be observed or the application will not be accepted. If an exception to this requirement is necessary, provide a brief explanation.

For program information contact:

Dr. Robert G. Burnight
Program Director
Career Development Unit
Cancer Control Applications Branch
Division of Cancer Prevention and Control
National Cancer Institute
Blair Building - Room 1A09
9000 Rockville Pike
Bethesda, Maryland 20205

Telephone (301) 427-8788

For grants administration information contact:

Mr. William Wells
Grants Management Specialist
Grants Administration Branch
Office of the Director
National Cancer Institute
Westwood Building - Room 855
5333 Westbard Avenue
Bethesda, Maryland 20205

Telephone (301) 496-7800

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

84-CA-08

CANCER CONTROL RESEARCH UNITS

P.T. 34; K.W. 1200270, 1200280, 1200460, 1002014, 0701042, 0701013, 0413000

NATIONAL CANCER INSTITUTE

Application Receipt Date: December 3, 1984

Letters of Intent Receipt Date: July 2, 1984

The Division of Cancer Prevention and Control (DCCP) of the National Cancer Institute (NCI) invites grant applications from interested investigators for the support of Cancer Control Research Units(CCRU). This RFA is a reissue of the CCRU RFA announced in the NIH Guide for Grants and Contracts, Volume 12, No. 9, September 23, 1983.

The goal of this RFA is to establish CCRU which will plan and implement focused research studies aimed at major cancer control problems. Cancer control is defined as the reduction of cancer incidence, morbidity, and mortality through an orderly sequence from research on interventions and their impact in defined populations to the broad, systematic application of the research results. The research will address cancer control interventions with potential for reducing cancer incidence, morbidity and/or mortality, and for generalizability to larger populations. The CCRU will be a long term resource for research and training for the Cancer Control Program of NCI.

The proposed CCRU should have one or more clearly identified "themes" or "programs", each consisting of an integrated group of projects from cancer control research phases II thru V (see below). The general areas of DCPC's cancer control research interest are described in Cancer Control Program Guidelines which were issued in July 1983.

The required components of a CCRU will include:

- o A rationale for the CCRU in terms of the cancer control themes and problems which will be investigated.
- o A CCRU Director with research and administrative experience.
- o A multidisciplinary cancer control research team of qualified investigators, and an underlying research base.
- o At least three high quality research projects which are approved with the CCRU application, of which two must be defined population studies;
- o Organizational, administrative and institutional procedures, committments and support.

CANCER CONTROL RESEARCH UNIT

Optional components of a CCRU are:

- Limited developmental or research projects, including applied epidemiology studies.
- Shared resource cores which are integral to two or more projects.
- The general objectives of the cancer control research phases and examples of the types of requirements needed to meet these objectives are summarized as follows:

PHASE	TITLE	OBJECTIVE	REQUIREMENTS
I	Hypothesis Development	To develop hypotheses grounded on scientific evidence	Etiologic or other evidence of of cancer problems. Potential interventions to test.
II	Methods Development and Testing	To validate methods needed to test the hypothesis	Proposed methods to reach and retain the target population. Proposed intervention(s) methods which need validation. Careful study designs which demonstrate reproducibility and accuracy of methods.
III	Controlled Intervention Trials	To determine the potential efficacy of interventions which have been validated	Demonstration of a significant intervention effect compared to control group.
IV	Defined Population Studies	To determine the probably effectiveness of interventions if applied on a broader scale to a larger population	An intervention with proven efficacy. A defined population representative of a larger population. Appropriate sampling design for extrapolation of results. Demonstration of a significant intervention effect compared to control group.
IV	Demonstration and Implementation Studies	To reduce cancer rates by the broad systematic application of effective interventions	A system for tracking cancer rates in the large population under study. An appropriate research design. An intervention successfully tested in Phase IV studies.

CANCER CONTROL RESEARCH UNIT

The CCRU will be encouraged to establish cancer control research training programs, including field involvement and applications. At this time, however, there will be no funds specifically earmarked for training within the CCRU grant, and potential applicants are encouraged to seek peer-reviewed support through the NCI traininggrant mechanisms. After the CCRU grants are awarded and underway, spin-offs such as training programs may develop.

Applicants are strongly encouraged to submit a letter of intent and consult with NCI program staff before submitting an application because of the need for a clear understanding of cancer control research issues and the P50 guidelines, and to facilitate planning for the review of applications.

Non-profit and for-profit institutions within the United States are eligible to apply for project periods of up to five years. Funds have been set aside during Fiscal Year 1985 to fund the initial year's awards. It is anticipated that a maximum of five awards will be made as a result of this RFA, subject to availability of funds. This RFA is the successor to the RFA entitled "Cancer Control Research Units for Defined Population Studies" which was previously announced in the NIH Guide for Grants and Contracts (Vol. 11, No. 2, January 29, 1982, page 15-18).

Copies of the complete RFA and the 1983 Cancer Control Program Guidelines (NIH Publication No. 84-2659, February 1984) may be obtained from:

Carlos E. Caban, Ph.D.
Program Director
Cancer Control Applications Branch, DCPC
National Cancer Institute
National Institutes of Health
Blair Building - Room 1A01
9000 Rockville Pike
Bethesda, Maryland 20205

Telephone: (301) 427-8735

ANNOUNCEMENT

THE NCI OUTSTANDING INVESTIGATOR GRANT

P.T. 34; K.W. 1002014, 1200180

NATIONAL CANCER INSTITUTE

Application Receipt Date: July 15

Letter of Intent Receipt Date: May 1

I. SUMMARY AND PURPOSE

The National Cancer Institute (NCI) announces the availability of the Outstanding Investigator Grant (OIG) for the purpose of providing long-term support to experienced investigators with outstanding records of research productivity. The initiation of this grant is intended to encourage investigators to embark on projects of unusual potential in cancer research. Emphasis will be placed on evidence of recent substantive contributions, i.e., seminal ideas and innovative approaches to resistant problems.

II. ELIGIBILITY

A. Candidate

Applications may be made by domestic institutions on behalf of investigators who have recently demonstrated outstanding research productivity for at least five years. There are no age restrictions. Only United States citizens, nationals or permanent residents may be presented as candidates for this grant.

B. Letter of Intent

Prospective applicants are strongly encouraged to submit a one to two page letter of intent, accompanied by a curriculum vitae and bibliography. This will enable the Institute to plan the review and advise applicants regarding their eligibility for consideration. Letters should provide a brief statement of the investigator's accomplishments, plus a brief general statement of the project(s) expected to be undertaken with the OIG support. Though application for a Public Health Service (PHS) Grant may be submitted without prior notification of intent, such letters would be appreciated.

Candidates considered to be ineligible based on the stated criteria and the letter of intent will be so informed by the Director, DEA, NCI.

A prospective candidate considered eligible will be so advised and invited to submit an Application for a PHS Grant (PHS 398).

III. PROVISIONS OF THE GRANT

The OIG is nontransferable and is awarded for a maximum period of seven years. The grant is not a lifetime award but is renewable. Application for competitive renewal should be submitted at the end of the fifth year according to the guidelines for the initial award.

The actual dollar award will reflect specifically the investigator's current and projected research needs evaluated by the Initial Reviewers, and reviewed by the Executive Committee, NCI. The award will provide that fraction of the investigator's salary that approximates the total proportion of salary awarded through current grants, but not to exceed 75%. This limit may be waived under exceptional conditions such as evidence of institutional provision of unusual levels of support of other types.

Funds will be provided for the support of technical staff, research staff and graduate students, but not for other academic faculty or institute equivalents. Salaries of other principal investigators may not be included. Other expenses, as would be included in individual project grants, are legitimate costs.

It is required that the OIG Principal Investigator will commit at least 75% of his/her time and effort to the research supported by this instrument.

Candidates for this award may concurrently apply for additional NIH research grant or research contract support for the balance of his/her time and effort, provided the requirement that the candidate institution provide 25% salary support has been waived. Renegotiation of all concurrent NIH funds upon acceptance of this grant is required.

Candidates for this award may concurrently apply for training grants, construction grants and capital equipment grants.

IV. REVIEW PROCEDURES AND CRITERIA

A. Review Method

Applications submitted in response to this Announcement will be assigned to an appropriate subset of a nationwide panel of recognized cancer investigators for review. The summary statements from this Initial Review Group will be submitted by the Executive Secretary, DEA, NCI, to the NCI Executive Committee to prepare its funding recommendations for the National Cancer Advisory Board (NCAB). The NCAB will recommend awards to the Director, NCI, for final action.

B. Review Criteria

Reviewers will consider the following factors in evaluating the scientific merit of each response to this Announcement:

1. What has been the impact of the applicant's work on the field of biomedical research?

a. Is his/her research cited often and as incentives for other's research efforts?

b. Has the applicant developed new experimental approaches crucial to the progress of his/her area of research?

c. Has he/she contributed to the collection of important reliable data?

d. In what way is the applicant's work seminal in nature?

e. Has the applicant productively exploited his/her own breakthroughs and/or those of others?

f. Has the applicant demonstrated imagination, energy, and sensitivity to the potential of serendipitous findings?

2. What will be the significance of the investigator's continued work in the field described above?

a. Does the proposed work break new ground or continue previous work?

b. Are the questions posed of significant interest and importance to cancer research?

c. Will this work provide impetus for others working in related areas?

3. Is there a strong likelihood that the investigator will continue at the frontiers of research?

C. Evaluation of the Capabilities of the Applicant

1. Comment on the way in which the applicant has achieved his/her present stature in the field. Speak both to the individual accomplishments and to collaborative interactions.

2. Has the applicant made significant contributions in the areas of teaching and research training and/or clinical research? Comment on the applicant's communicative, pedagogic, and organization skills.

D. Institutional and Administrative Relationships

1. Does the applicant have adequate administrative support?

2. Have the applicant investigator and his/her institution presented a workable plan for phase-out of the applicant's current research support and conversion of staff and facilities to support by the OIG? Are there any problems anticipated? Will there by any particular benefits or disadvantages for the institution?

V. HOW TO APPLY

Application for this award should be made on form PHS 398 (Rev. 5/82) in accordance with instructions in this Announcement. These applications are available in the business or contracts offices at most academic or research institutions, or from:

Division of Research Grants
National Institutes of Health
Bethesda, Maryland 20205

The title, **"NCI OUTSTANDING INVESTIGATOR GRANT"** should be typed in section 2 on the first page of the application. The date for receipt of applications is July 15 of each year.

The research proposal must be cancer-related as defined by the Division of Research Grants (DRG) grant application referral guidelines. Its prose portion should not exceed five typewritten single spaced pages.

A letter indicating clear and continuing institutional commitment to the applicant must be submitted. This commitment should include salary support at least to the current level, but may not be less than 25 percent. This minimum salary requirement may be waived under exceptional provision of unusual levels of support of other types. Adequate physical facilities, staff and administrative resources appropriate to the role of the OIG awardee must be provided.

The original and six copies of the application should be submitted to DRG, NIH, as directed in the instructions of the grant application.

VI. INQUIRIES

Please direct inquiries related to further information, application development or letter of intent to:

Mrs. Barbara S. Bynum
Director
Division of Extramural Activities
National Cancer Institute
Building 31 - Room 10A03
Bethesda, Maryland 20205

Telephone: (301) 496-5147

ANNOUNCEMENT

MOLECULAR RESEARCH IN STRABISMUS, AMBLYOPIA, AND VISUAL PROCESSING

P.T. 34; K.W. 1002046, 0701038, 1200470, 1200890, 1200900, 1201010, 1201030, 1201150

NATIONAL EYE INSTITUTE

The National Eye Institute (NEI) would like to encourage the submission of research project grant applications for molecular studies in Strabismus, Amblyopia, and Visual Processing. New knowledge derived from neuroanatomical and neurophysiological studies of the visual system and the development of several new techniques, including monoclonal antibody production, more sensitive means of measuring enzyme activity, and recombinant DNA techniques, suggest that additional molecular research on the visual processing and oculomotor systems is likely to lead to a more profound knowledge of the structure and function of these systems.

Listed below are some of the key areas that have been designated as targets for increased molecular research activity in the Strabismus, Amblyopia, and Visual Processing Program:

- Investigate the development of the visual system at the molecular level.
- Analyze the effects of visual deprivation or abnormal stimulation at the molecular level.
- Identify neurotransmitters, peptides, and other chemicals important in signaling between cells in the visual pathways.
- Identify molecules involved with cell specificity and function in the visual processing and oculomotor systems.
- Describe at the molecular level the development of the oculomotor system.
- Study the influence of drugs on neurotransmitters in normal and abnormal oculomotor subsystems.
- Examine the molecular characteristics of extraocular muscles; examine their molecular organization and function in normal and pathological conditions.
- Study pharmacological treatments of strabismus.

This program is described in the Catalog of Federal Domestic Assistance No. 13.871, Strabismus, Amblyopia and Visual Processing. Awards will be made under the Authority of the Public Health Service Act, Title III, Part A, Section 301, Public Law 78-410, as amended; (42 USC 241) and administered under PHS Grants Policies and Federal Regulation 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to Health Systems Agency review.

Vision Research--A National Plan: 1983-1987, Volume Two/Part Five provides more information about the program development priorities of the Strabismus, Amblyopia, and Visual Processing Program. Copies of this volume can be obtained by writing to:

Mr. Julian Morris
Office of Program Planning and Evaluation
National Eye Institute
Building 31 - Room 6A25
National Institutes of Health
Bethesda, Maryland 20205

I. MECHANISM OF SUPPORT

The mechanism of support for this program will be the individual research grant (R01's - Research Project Grant and R23's - New Investigator Research Grant).

II. APPLICATION AND REVIEW PROCEDURES

A. Deadline

Applications will be accepted in accordance with the usual receipt dates for new research grant applications. The earliest possible award dates will be approximately nine months after the respective receipt dates. Applications received too late for one cycle of review will be held until the next receipt date. This announcement will be effective for two years following the initial receipt date of July 1, 1984.

B. Method of Applying

Applications will be received by the NIH's Division of Research Grants (DRG) and referred to an appropriate study section for scientific and technical merit review. Institute assignment decisions will be governed by normal programmatic considerations as specified in the NIH Referral Guidelines. The review criteria customarily employed by the NIH for regular grant applications will prevail.

Following the initial scientific review, the applications will be evaluated by the applicable National Advisory Council.

Applications should be submitted on form PHS 398 (revised 5/82) which is available in the business or grants and contracts offices at most academic and research institutions or from the DRG. To identify the application as a response to this announcement, check "yes" in item 2 on the face page of the application and enter the title "Molecular Research in Strabismus, Amblyopia, and Visual Processing". The original and six (6) copies of the application should be directed to:

Application Receipt Office
Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

Inquiries should be directed to:

M. Janet Cardenas, Ph.D.
Strabismus, Amblyopia, and Visual
Processing Program
National Eye Institute
Building 31 - Room 6A49
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-5301

ANNOUNCEMENT

RESEARCH ON BASIC MECHANISMS OF RETINAL PHOTOTOXICITY

P.T. 34; K.W. 1002046, 0202022, 0404002, 1200110, 1200750, 1200780

NATIONAL EYE INSTITUTE

The National Eye Institute (NEI) wishes to encourage research which seeks to understand the basic mechanisms of how the metabolic status of the retina influences the susceptibility of photoreceptor cells to damage by light energy. It is important to differentiate between the way in which intrinsic factors (metabolic and nutritional) and extrinsic factors (light energy) may contribute to aging, retinal degeneration, and macular degeneration. This research area is of high programmatic interest to the NEI and its significance is addressed in the report of the National Advisory Eye Council, Vision Research--A National Plan: 1983-1987, Volume Two, Part One. Some of the program development priorities related to this announcement include: examination of the effects of light, age, drugs and antioxidants on lipofuscin (Chapter 8, Retinal Pigment Epithelium); investigation of environmental and nutritional factors affecting photoreceptor function, degeneration, and aging (Chapter 9, Photoreceptors, Visual Pigments, and Phototransduction); studies on retinal metabolism and biochemical processes critical to retinal function (Chapter 10, Retinal Organization, Neurotransmission, and Adaptation).

I. BACKGROUND

Photoreceptor disc membranes have an unusually high content of unsaturated phospholipids. These as well as other membrane components are constantly shed from the outer segments of the visual cells and phagocytized by the retinal pigment epithelium. The normal process of disc membrane turnover requires these polyunsaturated lipids to be catabolized by the pigmented epithelium which degrades and disposes of ingested membrane components. When the unsaturated lipids of these highly specialized biological membranes become oxidized by absorption of electromagnetic radiation, they may become cytotoxic. The shorter (high energy) wavelengths are especially efficient in this regard. Toxic debris may become deposited in the subretinal space and in the pigmented epithelium with possible consequences on degeneration of this tissue. Thus it is important to know how lipids may be altered by interactions with light and to what extent the accumulation of altered biomolecules contribute to cell damage.

This program is described in the Catalog of Federal Domestic Assistance No. 13.867, Retinal and Choroidal Diseases Research. Awards will be made under the authority of the Public Health Service Act, Title III, Part A, Section 301, Public Law 78-410, as amended; (42 USC 241) and administered under PHS Grants Policies and Federal Regulation 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to Health Systems Agency review.

Photoreceptor cells contain vitamin E as well as several other antioxidants such as selenium which may function in a protective capacity to prevent buildup of toxic molecules. Nutritional deficiencies which deplete vitamins A and E, taurine, selenium and zinc may cause photoreceptor degeneration, but the mechanisms are unclear. Monkeys on diets deficient in xanthophyll, an important component of macular pigment, develop abnormalities of the macula. These and other animal studies suggest that diet might also influence the progression of human aging-related maculopathy. Studies of the possible relationships between nutrition and the maintenance of optimal photoreceptor function are, therefore, important and of high programmatic interest to the NEI

Vision Research--A National Plan: 1983-1987, Volume Two/Part One provides more information about the program development priorities of the Retinal and Choroidal Diseases Program. Copies of this volume can be obtained by writing to:

Mr. Julian Morris
Office of Program Planning and Evaluation
National Eye Institute
Building 31 - Room 6A25
National Institutes of Health
Bethesda, Maryland 20205

II. MECHANISM OF SUPPORT

The mechanism of support for this program will be the individual research grant (R01's - Research Project Grant and R23's - New Investigator Research Grant).

III. APPLICATION AND REVIEW PROCEDURES

A. Deadline

Applications will be accepted in accordance with the usual receipt dates for new research grant applications. The earliest possible award dates will be approximately nine months after the respective receipt dates. Applications received too late for one cycle of review will be held until the next receipt date. This announcement will be effective for two years following the initial receipt date of July 1, 1984.

B. Method of Applying

Applications will be received by the NIH's Division of Research Grants (DRG) and referred to an appropriate study section for scientific and technical merit review. Institute assignment decisions will be governed by normal programmatic considerations as specified in the NIH Referral Guidelines. The review criteria customarily employed by the NIH for regular research grant applications will prevail.

Following the initial scientific review, the applications will be evaluated by the applicable National Advisory Council.

Applications should be submitted on form PHS 398 (revised 5/82) which is available in the business or grants and contract offices at most academic and research institutions or from the DRG. To identify the application as a response to this announcement, check "yes" in item 2 on the face page of the

application and enter the title **"Research on Basic Mechanisms of Retinal Phototoxicity'.** The original and six (6) copies of the application should be directed to:

Application Receipt Office
Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

Inquiries should be directed to:

Peter A. Dudley, Ph.D.
Program Director
Fundamental Retinal Processes Program
Retinal and Choroidal Diseases Branch
National Eye Institute
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-5983

ANNOUNCEMENT

VERGENCE EYE MOVEMENTS

P.T. 34; K.W. 1002001, 1002034, 0414003, 1200470, 1200410

NATIONAL EYE INSTITUTE

The National Eye Institute (NEI) would like to encourage the submission of research project grant applications for studies on the vergence eye movement system. Research on vergence eye movements is an important part of the Strabismus, Amblyopia, and Visual Processing Program; several areas of emphasis are listed in Vision Research--A National Plan: 1983-1987 and are outlined below. These include anatomical, physiological, and behavioral studies of vergence, determination of the factors that are significant in the development of vergence, and elucidation of the relationship between vergence and other ocular disorders, such as strabismus and amblyopia.

Persons with normal binocular vision respond to near objects of interest by converging their eyes to position images on the two foveas. Significant disorders of the vergence system are relatively common and may affect almost as many people as are affected by refractive errors. Disorders of the vergence system include symptom-producing heterophorias; strabismus; and fusional vergence anomalies. Associated symptoms include asthenopia, diplopia, suppression, amblyopia, and loss of depth perception.

The complexity of the vergence system and its component interactions, as well as interactions with accommodation, versions, and the vestibular system, has made research in this area difficult, and there has been considerably less research activity on vergence eye movements than on conjugate eye movements. Nonetheless, steady progress has been made in studies of vergence, and there now is basis to believe that research efforts on the mechanisms of vergence are likely to be very productive. Furthermore, the relationships among various disorders of vergence, including the characteristic and causes of strabismus, can be fruitfully explored at this time. Research on vergence eye movements is likely to benefit from the modification and application to the vergence system of approaches that previously have been valuable in studies of conjugate eye movements, as well as the design and application of entirely new approaches to study vergence.

This program is described in the Catalog of Federal Domestic Assistance No. 13.871, Strabismus, Amblyopia and Visual Processing. Awards will be made under the authority of the Public Health Service Act, Title III, Part A, Section 301, Public Law 78-410, as amended; (42 USC 241) and administered under PHS Grants Policies and Federal Regulation 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to Health Systems Agency review.

Some program development priorities related to vergence are:

- o Define in detail the vergence stimuli for neonates, children, and adults, and characterize the developing motor responses.
- o Elucidate the accommodative/vergence relationships in the neonate and ascertain the critical period for influencing this synkinesis.
- o Explain the mechanisms responsible for (1) plasticity of anomalous retinal correspondence associated with certain, but not all, vergence movements, and (2) the relative rigidity of normal correspondence in strabismics and nonstrabismics.
- o Study the basic anatomy, physiology, and behavior of the vergence system in appropriate animal models.

Additional information about the National Eye Institute's interest in research concerning vergence can be found in Vision Research--A National Plan: 1983-1987, Volume Two/Part Five, copies of which can be obtained by writing to:

Mr. Julian Morris
Office of Program Planning and Evaluation
National Eye Institute
Building 31 - Room 6A25
National Institutes of Health
Bethesda, Maryland 20205

I. MECHANISM OF SUPPORT

The mechanism of support for this program will be the individual research grant (R01's - Research Project Grant and R23's - New Investigator Research Grant).

II. APPLICATION AND REVIEW PROCEDURES

A. Deadline

Applications will be accepted in accordance with the usual receipt dates for new research grant applications. The earliest possible award dates will be approximately nine months after the respective receipt dates. Applications received too late for one cycle of review will be held until the next receipt date. This announcement will be effective for two years following the initial receipt date of July 1, 1984.

B. Method of Applying

Applications will be received by the NIH's Division of Research Grants (DRG) and referred to an appropriate study section for scientific and technical merit review. Institute assignment decisions will be governed by normal programmatic consideration as specified in the NIH Referral Guidelines. The review criteria customarily employed by the NIH for regular research grant applications will prevail.

Following the initial scientific review, the applications will be evaluated by the applicable National Advisory Council.

Applications should be submitted on form PHS 398 (revised 5/82) which is available in the business or grants and contracts offices at most academic and research institutions or from the DRG. To identify the application as a response to this announcement, check "yes" in item 2 on the face page of the application and enter the title **"Vergence Eye Movements".** The original and six (6) copies of the application should be directed to:

Application Receipt Office
Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

Inquiries should be directed to:

M. Janet Cardenas, Ph.D.
Strabismus, Amblyopia, and Visual
Processing Program
National Eye Institute
Building 31 - Room 6A49
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-5301

ANNOUNCEMENT

IMMUNOLOGICAL ASPECTS OF OCULAR DISEASE

P.T. 34; K.W. 1200470, 1002023, 1200670, 1201290

NATIONAL EYE INSTITUTE

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

The National Eye Institute (NEI) and the National Institute of Allergy and Infectious Diseases (NIAID) invite qualified investigators to submit research grant applications for the support of studies which seek to gain a better understanding of the role of the immune system both in the normal and diseased eye. Such a need has likewise been expressed by the National Advisory Eye Council when that body identified a number of important research areas in ocular immunology which require expansion in its most recent program planning report Vision Research--A National Plan: 1983-1987. This document focuses on the ongoing requirement for additional investigations which involve immunological approaches to the understanding, treatment and prevention of ocular diseases and calls for recruitment of additional immunologists to vision research in order to conduct these critical laboratory and clinical studies.

I. BACKGROUND

The eye presents a unique organ for immunological study since several of its component structures at developmental maturation, namely, the cornea, lens and vitreous are free of both blood and lymphatic vessels. The normal isolation of these structures from routes which are in direct contact with the reticulo-endothelial system alter the way that these tissues respond to foreign substances, whether desirable, such as exposure to transplanted tissue or undesirable, such as invasion from infecting viruses, bacteria or fungi. Alteration and/or breakdown of the normal functioning of the ocular immune system may represent an important factor in the development and spread of various eye cancers including choroidal melanoma and retinoblastoma.

This program is described in the Catalog of Federal Domestic Assistance No. 13.868, Corneal Diseases Research and No. 13.855, Immunology, Allergic and Immunologic Diseases. Awards will be made under the authority of the Public Health Service Act, Title III, Part A, Section 301, Public Law 78-410, as amended; (42 USC 241) and administered under PHS Grants Policies and Federal Regulation 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to Health Systems Agency review.

Vision Research--A National Plan: 1983-1987, provides more information about the program development priorities of the NEI with respect to ocular immunology. Copies of this plan can be obtained by writing to:

Mr. Julian Morris
Office of Program Planning and Evaluation
National Eye Institute
Building 31 - Room 6A25
National Institutes of Health
Bethesda, Maryland 20205

II. RESEARCH GOALS AND SCOPE

Research proposals are currently requested on those topics in ocular immunology which have received priority identification from each of the five program areas of the National Eye Institute by the National Advisory Eye Council in its recent report entitled Vision Research--A National Plan: 1983-1987. These topics include: determining the neuronal and viral factors contributing to the latent period of ocular herpes infection; evaluating immunological mechanisms of the ocular surface of the eye and the role of such mechanisms in health and disease; improving the understanding of the biochemistry and immunological components of the cornea's response to injury and wound healing; determining the importance of specific immunological factors in corneal transplantation, and developing and testing drugs which can modify or eliminate immune reactions to transplanted tissue; assessing new drug and immunological approaches to the treatment and prevention of uveitis and inflammatory disorders; improving treatment of glaucoma secondary to uveitis through better understanding of the mechanisms of inflammation, and evaluation of the effectiveness of specific anti-inflammatory drugs in its treatment; pursuing new approaches to research on the basic biology, immunology, and genetics of sight- and life-threatening intraocular tumors; investigating the structure, function, and development of the visual system at the molecular level including studies of cellular receptor sites, cell specificity, neurotransmitters and peptides, and immunological approaches--with the ultimate aim of designing drug treatments for visual neurosensory disorders and injuries.

III. MECHANISM OF SUPPORT

The mechanism of support for this activity will be the individual research grant (R01's - Research Project Grant and R23's - New Investigator Research Grant) as applicable.

IV. APPLICATION AND REVIEW PROCEDURES

A. Deadline

Applications will be accepted in accordance with the usual receipt dates for new research grant applications. The earliest possible award dates will be approximately nine months after the respective receipt dates. Applications received too late for one cycle of review will be held until the next receipt date. This announcement will be effective for two years following the initial receipt date of July 1, 1984.

B. Method of Applying

Applications will be received by the NIH's Division of Research Grants (DRG) and referred to an appropriate study section for scientific and technical merit review. Institute assignment decisions will be governed by normal programmatic considerations as specified in the NIH Referral Guidelines. It is likely that most applications submitted in response to this announcement would receive dual Institute assignments. In general, applications dealing with ocular immunology where the focus is the visual disorder or function would be assigned to the NEI. Applications which focus on basic immune mechanisms would be assigned to the NIAID. The review criteria customarily employed by the NIH for regular research grant applications will prevail.

Following the initial scientific review, the applications will be evaluated by the applicable National Advisory Council.

Applications should be submitted on form PHS 398 (revised 5/82) which is available in the business or grants and contract offices at most academic and research institutions or from the DRG. To identify the application as a response to this announcement, check "yes" in item 2 on the face page of the application and enter the title **"Immunological Aspects of Ocular Disease."**The original and six (6) copies of the application should be directed to:

Application Receipt Office
Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

Inquiries should be directed to:

Ralph J. Helmsen, Ph.D.
Chief, Anterior Segment Diseases Branch
National Eye Institute
National Institutes of Health
Building 31 - Room 6A47
Bethesda, Maryland 20205

Telephone: (301) 496-5301

or

Robert A. Goldstein, M.D., Ph.D.
Chief, Allergy and Clinical Immunology Research
National Institute of Allergy and
Infectious Diseases
Westwood Building - Room 755
Bethesda, Maryland 20205

Telephone: (301) 496-7104

ANNOUNCEMENT

RESEARCH TRAINING AND DEVELOPMENT AREAS AND TYPES OF AWARDS AVAILABLE

P.T. 44,22,34; K.W. 0202022, 0404019, 0411005, 0701042, 1002019, 1002034, 1200170, 1200120, 1200240, 1200600, 1201090, 1201220

DIVISION OF HEART AND VASCULAR DISEASES

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

This announcement consolidates and summarizes the current research training and development programs of the Division of Heart and Vascular Diseases (DHVD) It is a summary intended to be helpful to potential applicants. It is not an announcement of new programs or initiatives. (The number of awards made annually will depend on merit and programmatic emphasis of proposals received, as well as the availability of funds.)

Research training may be in fundamental studies of basic processes and functions, behavioral studies, including risk factor modification (e.g. diet, smoking), genetics (including studies of populations), and primary and secondary prevention of clinical investigations directed toward increasing knowledge and understanding in any cardiovascular disease area. Division activities are categorized into one or more of the following program areas:

Arteriosclerosis
Hypertension
Coronary Heart Disease
Cardiovascular Aspects of Diabetes
Arrhythmias
Heart Failure and Shock
Cerebrovascular Disease
Congential and Rheumatic Heart Disease
Cardiomyopathies and Infections of the Heart
Circulatory Assistance
Cardiovascular Devices and Technology

The awards summarized below may be used for the support of research training and development in the areas listed above.

These programs are described in the Catalog of Federal Domestic Assistance No. 13.837, Heart and Vascular Diseases Research. Awards will be made under the authority of the Public Health Service Act, Section 472 (42 USC 2891-1), and administered under PHS grants policy and Federal Regulations 42 CFR Part 66; and Section 301 (Public Law 78-410, as amended; 42 USC 241), administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. These programs are not subject to Health Systems Agency review.

RESEARCH TRAINING AND DEVELOPMENT BRANCH PROGRAMS

I. National Research Service Award Programs

A. Institutional Research Training Grant Award

- Predoctoral and postdoctoral trainees.
- Selection of training institution by national competition.
- Institutional selection of trainees.
- Trainee support includes stipend ($5,292 per year for predoctoral trainees; $14,040-$19,716 per year for postdoctoral trainees depending on relevant postdoctoral experience), tuition, fees, health insurance, and travel.
- Stipend supplementation is allowed from non-federal funds.
- Institutional support; indirect cost is limited to 8 percent.
- Duration of award may be up to five years.
- Maximum predoctoral training duration is five years.
- Maximum postdoctoral training duration is three years.
- Each month of NRSA-financed training after the first 12 months requires a month of payback activity in biomedical or behavioral teaching and/or research.
- Receipt dates for applications are:

	Advisory Council Review
February 1	October
June 1	February
October 1	May

B. Individual Postdoctoral Fellowship Award

- Postdoctoral trainees only.
- Selection by national competition.
- Stipend is $14,040-$19,716 depending on relevant postdoctoral experience.
- Stipend supplementation is allowed from non-federal funds.
- Institutional support.
- Duration of award is one to three years.
- Maximum training duration is 36 months.
- Each month of NRSA-financed training after the first 12 months requires a month of payback activity in biomedical or behavioral teaching and/or research.
- Receipt dates for applications are:

	Results announced in:
February 1	August
June 1	December
October 1	April

C. Senior Research Fellowship Award

- To make major changes in direction of research careers or to acquire new research capabilities.
- Experienced scientists only (at least seven years of relevant postdoctoral research or professional experience).
- Selection by national competition.
- Stipend will be negotiated up to $30,000 per year.
- Stipend supplementation is allowed from non-federal funds.
- Institutional support.
- Duration of award is normally twelve months.
- Each month of NRSA-financed training after the first 12 months requires a month of payback activity in biomedical or behavioral teaching and/or research.
- Receipt dates for applications are:

	Results announced in:
February 1	August
June 1	December
October 1	April

D. Short-Term Research Training: Students in Health Professional Schools

- To increase the number of clinical investigators in biomedical and behavioral research careers.
- Qualified health professional students only.
- Selection of training institutions by national competition.
- Institutional selection of trainees.
- Stipend support for trainees ($441 per trainee per month for 2-3 months); institutional allowance up to $125.00 per trainee per month.
- Stipend supplementation is allowed from non-federal funds.
- No award made for fewer than four nor more than thirty-two students per year.
- Duration of award may be up to five years.
- No payback provision for training periods of up to three months.
- Application receipt date of February 1 each year with a May 1 award date the following year.

II. The Research Career Development Programs

A. Research Career Development Award

- Research career development of biomedical or behavioral scientists with outstanding research potential.
- Cannot be an established independent investigator when awarded.
- Must have at least three years postdoctoral experience.
- Selection by national competition.
- Salary support of up to $30,000 per year plus fringe benefits.
- Supplementation is allowed from non-federal funds.

- Duration of award is five years; non-renewable.
- Must devote essentially full time to research and research-related activities.

- Receipt dates for applications are:

	Advisory Council Review
February 1	October
June 1	February
October 1	May

B. Clinical Investigator Award

- To encourage newly trained clinicians to develop clinical and basic research interests and skills in the area of cardiovascular diseases.
- Newly trained physicians are candidates for the award.
- Selection by national competition.
- The grantee institution must have strong, well-established research and training programs.
- Candidates must have one or more sponsors or advisors from the grantee institution.
- Salary support of up to $30,000 per year plus fringe benefits.
- Supplementation is allowed from non-federal funds.
- Support for five years; full time effort; non-renewable.
- Minimum of 75 percent effort to the research program.

- Receipt dates for applications are:

	Advisory Council Review	Earliest Beginning Date
February 1	October	December 1
June 1	February	April 1
October 1	MayJ	July 1

C. Physician Scientist Award

- To encourage individuals with clinical training to develop research skills in a fundamental science.
- Candidates must have a health professional degree such as M.D. or D.O.; physicians holding the Ph.D. degree are not eligible.
- Selection by national competition.
- The grantee institution must have strong, well-established research and training programs in clinical and basic sciences.
- Candidates must have one or more sponsors in a basic science research area.
- Salary is up to $30,000 per year plus fringe benefits.
- Supplementation is allowed from non-federal funds.
- Support for five years; non renewable.
- Minimum of 75 percent effort to the research program.
- Awardee and sponsor must submit special detailed progress report at end of third year.

	Receipt dates for applications are:	Advisory Council Review	Earliest Beginning Date
o	February 1	October	December 1
o	June 1	February	April 1
o	October 1	May	July 1

D. Preventive Cardiology Academic Award

- o To encourage development of high quality preventive cardiology curriculum in schools of medicine and osteopathy that will attract outstanding students to preventive cardiology research and medical practice.
- o The awardee must hold an academic appointment at a school of medicine or osteopathy and have clinical training as well as research and teaching experience in cardiology.
- o The institution must sponsor a candidate with competence in clinical cardiology and provide the awardee with time to acquire the educational skills for personal development as a teacher and for the development of the preventive cardiology curriculum.
- o Awards are limited to one for each eligible school with a project period of five years.
- o Awardee must devote at least 50 percent time or effort.
- o Salary support of up to $30,000 per year plus fringe benefits.
- o Supplementation is allowed from federal funds.
- o Award provides funds for some other operating costs.
- o Annual receipt date of April 1 for starting date of July 1 the following year.

E. Special Emphasis Research Career Award: Diabetes Mellitus

- o To encourage qualified individuals to develop interdisciplinary research skills in Diabetes Mellitus.
- o Applicant must hold an M.D. or equivalent professional degree with a minimum of three years post-M.D. experience or two years post-M.D./Ph.D. experience.
- o Selection by national competition.
- o Support for five years; non-renewable
- o Full-time salary support up to a maximum of $30,000 per year.
- o Supplementation is allowed from non-federal funds.
- o Research support for first three years up to a maximum of $8,000 per year; research support for 4th and 5th year up to a maximum of $20,000 per year.
- o Annual receipt date of June 1. Advisory Council review in February.

III. Development-Related Program

Although not a training or development grant per se, the New Investigator Research Award (NIRA) may be used to bridge the transition from training status to that of an established investigator. The NIRA has the following features:

- To encourage new investigators in basic or clinical science disciplines to develop their research interests and capabilities in biomedical and behavioral research and not more than 5 years research experiences after completing formal training.
- Doctoral degree by time of award.
- Restricted to applicants who have not previously been principal investigators on a PHS supported project.
- Concurrent applications not permitted for research grant award, research training or research development award.
- Duration of award up to the three years; non-renewable.
- Salary support up to $25,000 per year; total direct cost must not exceed $107,500 for three year period - no more than $37,500 in any one year.
- Supplementation is allowed from non-federal funds.
- Selection by national competition.
- Receipt dates for applications are:

	Advisory Council Review:
March 1	October
July 1	February
November 1	May

Further information regarding the above programs can be obtained from:

Research Training and Development Branch
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
National Institutes of Health
Federal Building - Room 3A08
Bethesda, Maryland 20205

Telephone: (301) 496-1724

ANNOUNCEMENT

STUDIES ON OBESITY

P.T. 34; K.W. 1200930, 0202022, 1200460, 1002019, 1200890, 0404000

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISEASES
NATIONAL CANCER INSTITUTE
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE
NATIONAL INSTITUTE ON AGING
NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT
NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE
NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM
NATIONAL INSTITUTE ON DRUG ABUSE
NATIONAL INSTITUTE OF MENTAL HEALTH

I. BACKGROUND INFORMATION

Research on the biomedical and behavioral aspects of obesity is an important component of the NIH and ADAMHA nutrition research programs. Obesity is widely prevalent in the U.S. affecting both children and adults. Children today at one year of age are on the average, 50 percent heavier than they were a generation ago; 40 percent of American women and 32 percent of the American men between the ages of 40 and 49 years are at least 20 percent above desirable weight desirable weight defined by National Health and Nutrition Examination Survey (NHANES) as the average weight of those individuals between the ages of 20-29 years. Moreover, 7.2 percent of women and 4.9 percent of men aged 20-74 years were found to be severely obese in a U.S. survey using a national probability sample. Recent data from the second NHANES survey (1976 to 1980) indicate that the prevalence of obesity persists and that those in the 90th percentile are even heavier than in previous surveys.

Obesity is either a risk factor for, or is associated with, a number of diseases including diabetes, hypertension, coronary heart disease, complications of pregnancy, osteoarthritis, and some cancers and infections. Obesity may also be an adverse prognostic factor in certain diseases, such as early stage breast cancer and cancer of the endometrium.

II. RESEARCH GOALS AND SCOPE

The emphasis of this program announcement is the support of research on the biomedical and behavioral aspects of exogenous obesity. The goals of this research, which includes both basic and clinical research, are to establish a clear understanding of the etiology, prevention and treatment of this multifaceted condition. For example, the determinants of obesity during the early stages of the life cycle need to be identified in order to prevent the onset of obesity early in life and to identify individuals at high risk of becoming obese later in life. The question of whether obesity is a risk factor per se for the development of other disease states needs to be clarified as well as its relationship to mortality. Preventive therapies as well as successful treatment regimens need to be designed. In order to accomplish these goals, further research is needed on the behavioral and

developmental aspects of obesity in terms of its natural history and determinants in infancy, childhood, and adolescence; on the metabolic, genetic and neurological aspects of obesity; on the successful treatment of overnutrition and obesity; and on the effects of obesity on body weight, health and longevity. A major question with respect to the health implications of obesity in terms of body weight, health and longevity is one of determining the relative role of body build on the one hand and of "fatness" on the other on the morbidity and mortality attributed to obesity. Another problem is to learn more about the relationship of adipose tissue morphology and of the pattern of fat distribution to the impaired health and shortened life span associated with obesity.

Examples of research areas in overnutrition and obesity of particular interest follow:

A. METABOLIC AND GENETIC FACTORS

The metabolic and genetic factors related to obesity encompass dietary determinants (nutrient sources, intake and balance) that affect metabolism, particularly of the adipose cell, and its effect in turn on appetite; the effect of various physiological and genetic factors on eating behaviors and subsequent weight gain or weight control; the interactions between metabolic parameters and resulting maladaptive patterns of food ingestion and drug abuse; the mechanisms by which obesity contributes to the development of diseases such as diabetes, coronary heart disease, hypertension, cancer, etc.; and the determinants of genetic/biochemical markers for the different kinds of obesity.

B. NEUROLOGICAL AND ENDOCRINE FACTORS

In order to better understand the role of the central nervous system in the etiology of obesity, studies are encouraged to examine the neurophysiology of ingestive behaviors in terms of the neurochemical and neuroanatomical integrations at the level of the neuron and synapse, as well as the neuroanatomical pathways and neurological mechanisms of taste and smell that affect eating behaviors, and the effects of various drugs in their modification. In addition, studies on all aspects of satiety, anorexia, bulimia and bulimarexia are of special interest.

C. BEHAVIORAL AND DEVELOPMENTAL FACTORS

The need to elucidate the underlying causes of obesity requires investigations on behavioral, psychological, and developmental factors as well as on physiological, metabolic and neuronal factors as previously described. Knowledge of the role of all of these factors contributes to a better understanding of the necessary strategies for the prevention and treatment of obesity.

D. THE EFFECTS OF OVERWEIGHT/OBESITY ON HEALTH AND LONGEVITY

In the most recent analysis of the Framingham Heart Study data there is strong evidence that body weights in excess of those recommended as desirable by the 1959 Metropolitan Life Insurance Table are associated with increased mortality. There is a need to develop an appropriate data base relating body weight by age, sex, and possibly frame size to morbidity and

mortality, so as to permit the preparation of reference tables for defining the range of body weight based on morbidity and mortality statistics. Reference data should take into account appropriate attributes (physical activity level, nature of diet, etc.) as well as possible changes in the attributes. This will require new observational studies to quantify, in study populations, the relationship of such factors to morbidity and mortality.

Since obesity has been shown to be a significant independent predictor for cardiovascular disease, there is a need to: investigate the ways in which overweight becomes or acts as a "marker" for premature demise; define the effect of duration of overweight on health in order to ascertain the specific age (how early in life) at which overweight becomes a marker for morbidity and mortality; and identify the various types of obesity that are associated with specific diseases at different stages of the life cycle (e.g. upper trunk obesity with diabetes, fat cell number and hypertension in early adulthood and fat cell size and hypertension in middle age).

E. TREATMENT OF OBESITY

Due to the serious health implications of obesity, research must continue to find successful treatment measures for obesity and to prevent its recurrence. Various treatments that need to be examined include the use of hypocaloric regimens, the effects of exercise on metabolism and subsequent weight loss, and behavioral modification therapies. Such treatments need to be examined across the various stages of the life cycle, as well as in terms of their success and safety in maintaining weight loss without provoking or aggravating other medical disorders.

F. In the next section of this program announcement the research priorities in the aforementioned categories are presented by of each of the Institutes participating in this joint program announcement. However, these priorities are intended as examples of research interest and do not preclude the submission of applications involving other research approaches to the issues under consideration. In addition, this joint program announcement is not intended to discourage investigators from their pursuit of promising ideas in related topics.

METABOLIC AND GENETIC FACTORS

Examples of research interest are listed by Institute.

1. National Institute of Arthritis, Diabetes and Digestive and Kidney Diseases

   - Dietary determinants (nutrient sources, intake and balance) of the proliferation and control of depot fat cell size and number.

   - Mechanism of the effect of depot adipose cell size, adipocyte number, and overall body composition on appetite.

   - Physiological abnormalities (e.g. protein depletion) following weight loss and their role in promoting recidivism.

- The effect of mild exercise on appetite and its role in weight control.

- Individual variability in energy metabolism and thermogenesis.

2. National Cancer Institute

- Mechanisms by which overnutrition and obesity increases the risk of developing cancer.

- Mechanisms for the development of obesity in patients with breast cancer receiving adjuvant chemotherapy.

3. National Heart, Lung and Blood Institute

- Mechanisms by which obesity may act as an "independent" coronary heart disease risk factor apart from its known impact on other CHD risk factors (hypertension, hyperlipidemia, etc.)

- Mechanisms by which weight gain and overweight influence lipoprotein fractions when age, sex, physical activity, smoking, diet, genotype, etc. are considered.

- Mechanisms involved in the development of hypertension in overweight persons (endocrine/metabolic derangements, blood volume changes, electrolyte metabolism, etc.).

4. National Institute of Child Health and Human Development

- Genetic and physiological factors that influence weight gain and weight control during infancy, childhood, and adolescence.

5. National Institute on Alcohol Abuse and Alcoholism

- Mechanisms by which alcohol may alter metabolic homeostasis and contribute to the development of obesity.

6. National Institute on Drug Abuse

- Correlations and interactions between metabolic parameters and the resulting maladaptive patterns of food ingestion and psychoactive drug use.

- Changes in the effects of behaviorally active drugs as a function of weight loss and weight gain, e.g. their mobilization or storage as a function of these conditions.

7. National Institute of Mental Health

- Physiological factors that influence the development of anorexia nervosa and bulimia.

NEUROLOGICAL AND ENDOCRINE FACTORS

Examples of research interest are listed by Institute.

1. National Institute of Arthritis, Diabetes and Digestive and Kidney Diseases

   - o Physiological factors that affect eating behavior; hormones, metabolites and neuropeptides that are signals of satiety and hunger.

2. National Institute of Child Health and Human Development

   - o Neurochemistry and neurophysiology of the central nervous system in terms of the origin of the feelings of hunger and satiety, and the relationship to food ingestion and meal cessation.

3. National Institute of Neurological and Communicative Disorders and Stroke

   - o Mechanisms by which the structure and function of the neuron and synapse affect neuromuscular feeding behaviors in animals, e.g. swallowing.
   - o Role of the brain in mediating acquisition, extinction and aversion of associations to gustatory, olfactory and trigeminal stimulation.
   - o The electrophysiological activity of the brain resulting from changes in food intake in animals, as well as gustatory, olfactory and trigeminal stimulation.
   - o Neuroanatomical pathways connecting the gastrointestinal system to the hypothalamus, and the effect of changes in the gastrointestinal system on electrophysical activity in the hypothalamus.
   - o Neuroanatomical organizations and pathways of the somatic and autonomic nervous systems that control food intake and the behavioral, hormonal and metabolic mechanisms by which such pathways influence body weight.
   - o Abnormalities in the brain of genetically obese animals.
   - o Neurological mechanisms of taste and smell, and their common chemical reception and chemosensory stimuli in a variety of animal models.

4. National Institute on Drug Abuse

   - o The neurological basis of homeostasis for feeding control, and the effect of various behaviorally active drugs in modification of "set points" leading to nutritional changes.

5. National Institute of Mental Health

- Neuronal substrates and substances that influence eating behavior.

BEHAVIORAL AND DEVELOPMENTAL FACTORS

Examples of research interest are listed by Institute.

1. National Institute of Arthritis, Diabetes and Digestive and Kidney Diseases

- Psychological factors that influence the development and maintenance of overeating and bulimia, as well as in anorexia nervosa.
- The attributes of diet, such as nutrient imbalances or source, that promote hyperphagia.

2 National Cancer Institute

- Behavioral strategies to reduce dietary fat intake and their application to large population groups.
- Dietary composition that relates to the development of obesity and may increase the risk for developing certain kinds of cancer.

3. National Institute of Child Health and Human Development

- Psychological and social factors that influence weight gain and weight control during infancy, childhood, and adolescence.

4. National Institute on Alcohol Abuse and Alcoholism

- The relationship of eating disorders to alcohol abuse and alcoholism.

5. National Institute on Drug Abuse

- The specific patterns of types of drug use as a function of nutritional disorders.
- The development of obesity as either an antecedent or consequent to drug use.
- The relationship between eating disorders and other stereotypic disorders including drug use.
- The relationship between mood states, behavioral patterns, food intake and drug use.

6. National Institute of Mental Health

- Behavioral, psychological and social correlates of overeating and obesity.

- The relationship of stress responsiveness to overeating and obesity as well as the relationship of overeating and obesity to psychiatric illness.

THE EFFECTS OF OVERWEIGHT/OBESITY ON HEALTH AND LONGEVITY

Examples of research interest are listed by Institute.

1. National Institute of Arthritis, Diabetes and Digestive and Kidney Diseases

   - Examination of obesity as a risk factor for diseases such as diabetes, digestive diseases, degenerative joint or bone diseases, renal diseases and hypertension.

2. National Cancer Institute

   - Examination of the adverse prognostic effect of obesity in early stage breast cancer.

   - Determination of the types of cancer for which risk is increased by overnutrition and obesity.

3. National Heart, Lung and Blood Institute

   - Examination of different kinds of obesity (juvenile vs. adult onset) in terms of impact on hyperlipidemia, hypertension, and/or hyperglycemia, as well as the effects of weight reduction and long-term maintenance of lowered body weight on the reduction of hyperlipidemia, hypertension and other cardiovascular disease risk factors.

4. National Institute of Neurological and Communicative Disorders and Stroke

   - Examination of the relationship between obesity and stroke; i.e., is obesity in itself a risk factor for stroke or is it associated with other risk factors for this disease.

5. National Institute on Aging

   - The effect of overnutrition and the role of obesity on longevity in healthy humans and in suitable animal models.

   - The contribution of overnutrition to the aging of various organ systems.

6. National Institute of Mental Health

   - Interrelationship of overeating and obesity, stress responsiveness and psychiatric illness.

TREATMENT OF OBESITY

Examples of research interest are listed by Institute.

1. National Institute of Arthritis, Diabetes and Digestive and Kidney Diseases

   - Weight management strategies that include individuals with special dietary requirements due to their stage in the life cycle or to the existence of chronic diseases such as diabetes, renal disease, etc.

   - The effect of mild exercise on appetite and its relationship to weight control.

2. National Heart, Lung and Blood Institute

   - Treatment regimens that include both changes in diet and physical activity and also relate to other cardiovascular disease risk factors, both in terms of their treatment and prevention.

3. National Institute on Aging

   - The effects of weight loss regimens on health and longevity in the obese elderly.

4. National Institute of Child Health and Human Development

   - The use of hypocaloric dietary therapy for obese children and adolescents.

   - Behavioral intervention strategies to treat obesity in infancy, childhood and adolescence.

5. National Institute on Drug Abuse

   - Similarities and differences in successful programs designed to treat nutritional and substance abuse disorders.

6. National Institute of Mental Health

   - The behavioral, psychological and psychopharmacological treatment of overeating and obesity.

For further information, investigators are encouraged to contact one or more of the following individuals:

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISEASES

Van S. Hubbard, M.D., Ph.D.
Nutrition Program Director
Westwood Building - Room 3A18
Bethesda, MD 20205 (301) 496-7823

NATIONAL CANCER INSTITUTE

Ritva Butrum, Ph.D.
Program Director
Diet and Cancer Branch
Division of Cancer Prevention and Control
Blair Building - Room 619
Bethesda, MD 20205 (301) 427-8753

Freddie Ann Hoffman, M.D.
Program Director
Nutrition and Supportive Care Section
Division of Cancer Treatmemt
Landow Building - Room 4A18
Bethesda, MD. 20205 (301) 496-4844

John Cooper, Ph.D.
Chief, Extramural Programs Branch
Division of Cancer Etiology
Landow Building - Room 8C41
Bethesda, MD 20205 (301) 496-1882

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Barbara Packard, M.D., Ph.D.
Director, Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
Federal Building - Room 416A
Bethesda, MD 20205 (301) 496-2553

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Gilman D. Grave, M.D.
Chief, Nutrition and Endocrinology Section
Clinical Nutrition and Early Development Branch
Center for Research for Mothers and Children
Landow Building - Room 7C17
Bethesda, MD 20205 (301) 496-5575

NATIONAL INSTITUTE ON AGING

William A. Kachadorian, Ph.D.
Nutrition Section
Physiology of Aging Branch
Biomedical Research and Clinical Medicine Program
NIA, Building 31 - Room 5C27
Bethesda, MD 20205 (301) 496-9350

Leonard Jakubczak, Ph.D.
Behavioral Sciences Research Program
National Institute on Aging
Building 31 - Room 4C32
Bethesda, MD 20205 (301) 496-3136

NATIONAL INSTITUTE OF MENTAL HEALTH

Ellen Simon Stover, Ph.D.
Chief, Research Resources Branch
Division of Extramural Research Programs
National Institute of Mental Health
Parklawn Building - Room 10-104
5600 Fishers Lane
Rockville, MD 20205 (301) 443-4266

NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

Eugene Streicher, Ph.D.
Fundamental Neurosciences Program
National Institute on Neurological and Communicative Disorders and Stroke
Federal Building - Room 1C04
Bethesda, MD 20205 (301) 496-1447

III. MECHANISM OF SUPPORT

The mechanism of support for this program will be the grant-in-aid. The regulations (Code of Federal Regulations, Title 42, Part 52 and Title 45, Part 74) and policies that govern the research grant programs of the Public Health Service will prevail. The award of grants pursuant to this request for grant applications is contingent upon ultimate receipt of appropriated funds for this purpose.

IV. METHOD AND CRITERIA OF REVIEW

A. Assignment of Applications: Applications will be received by the Division of Research Grants (DRG), NIH, referred to an appropriate study section for scientific review, and assigned to individual Institutes for possible funding. These decisions will be governed by normal programmatic considerations as specified in the DRG Referral Guidelines.

B. Review Procedures: Applications in response to this announcement will be reviewed on a nationwide basis in competition with other applications received in the same review cycle, and in accord with the usual National Institutes of Health/Alcohol, Drug Abuse and Mental Health Administration peer review procedures. They will first be reviewed for scientific and technical merit by a review group composed mostly of non-Federal scientific consultants (study section). Following study section review, the application will be evaluated by the appropriate Institute Advisory Council or Board with respect to the adequacy of the technical merit review and the program relevance of the research proposed. The review criteria customarily employed by the National Institutes of Health/Alcohol, Drug Abuse and Mental Health Administration for regular research grant applications will prevail.

C. Deadlines: Applications will be accepted in accordance with the usual receipt dates for new applications:

March 1
July 1
November 1

V. METHOD OF APPLYING

Applications should be submitted on forms PHS 398 which is available in the business or grants and contracts office at most academic and research institutions, or on form PHS 5161 for state and local governments. The phrase **"PREPARED IN RESPONSE TO NIH/ADAMHA OBESITY PROGRAM ANNOUNCEMENT"** should be typed into item 2 of the first page of the application.

For NIMH areas of interest, applicants may apply for small grants in addition to regular research grants. For information about small grants contact the NIMH staff person listed in this announcement. The original and six copies of the application should be sent or delivered to:

Application Receipt Office
Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

For further information, investigators are encouraged to contact one or more of the Institute contacts listed above.

This program announcement replaces a previous one published in the NIH Guide for Grants and Contracts, Vol 7, No. 18, November 27, 1978.

ANNOUNCEMENT

ACADEMY OF FINLAND POSTDOCTORAL RESEARCH FELLOWSHIPS

P.T. 22, 48; K.W. 1200170, 1200180, 1200270

FOGARTY INTERNATIONAL CENTER

The Academy of Finland provides a limited number of research fellowships to U.S. biomedical scientists to conduct research in Finland. The purpose of these fellowships is to enhance the exchange of research experience and information in the biomedical sciences. The types of activity that are supported by this program include collaboration in basic or clinical research, and the familiarization with or utilization of special techniques and equipment not otherwise available to the applicant. The program does not provide support for activities that have as their principal purpose brief observational visits, attendance at scientific meetings, or independent study.

The program is administered for the Academy of Finland by the Fogarty International Center (FIC) National Institutes of Health (NIH).

I. ELIGIBILITY

Applicants for the program must meet the following requirements:

- o U.S. citizenship or permanent U.S. residency.
- o A doctorate in one of the behavioral or biomedical sciences.
- o Ten years or less of postdoctoral experience
- o Professional experience in the health sciences for at least two of the last four years.

II. SUPPORT

The Academy of Finland will provide the following support:

1. Stipend: Stipends are between FIM 108,000 and FIM 132,000 per annum.* The appropriate level is determined by the number of years of relevant or professional postdoctoral experience at the time of award. Research experience such as teaching, internship, or residency is considered relevant experience. Fellows may accept sabbatical salary, concurrent royalties, or other income from past services if reported in the application.

2. Travel: Roundtrip tourist class air fare expenses are provided for fellows and members of their families (spouse and dependent children)

*Equivalent to $18,400-$22,500 per annum as of February 1984.

from point of origin in the United States to the Finnish host institution(No reimbursement will be made for any other expenses enroute, nor for costs of transporting personal or household effects.)

3. Health Insurance. Health and accident insurance coverage are provided for fellows and dependents during their stay in Finland. Each fellow is strongly urged to purchase in the United States insurance to cover the round-trip transit period for himself/herself and accompanying family members.

III. DURATION OF PARTICIPATION

Fellowships are awarded for a 1 year period, but exceptions may be considered if recommended by the host institution and approved by the Academy of Finland. The starting date of the fellowships is set by mutual agreement of the applicant and the institution, provided it is within the 10 month period immediately following the date of the award.

IV. APPLICATION AND SELECTION

Information and application forms are provided by the FIC. In addition to biodata and reference reports, the applicant will be required to include a clear and explicit description of the proposed activity to be carried out in Finland and the benefits expected from the experience. It is the applicant's responsibility to arrange for his or her research program with the sponsor in Finland either through direct correspondence or through correspondence in the applicant's behalf by a senior scientist in the United States with a Finnish colleague. The sponsor's portion of the application should reflect that he or she is prepared to guide and administer the proposed research project, and can provide the necessary facilities.

The receipt date for applications at the FIC is October 1. Applications are reviewed for scientific merit by the NIH and are transmitted to the Academy of Finland for final selection. The selection meeting is held in June of the year following the receipt of applications. Shortly after the selection meeting candidates will be notified of the results.

V. INQUIRIES AND APPLICATION KITS

Chief, International Research and Awards Branch
Fogarty International Center
National Institutes of Health
Bethesda, Maryland 20205

ANNOUNCEMENT

NORWEGIAN RESEARCH COUNCIL FOR SCIENCE AND THE HUMANITIES

POSTDOCTORAL FELLOWSHIPS

P.T. 22, 48; K.W. 1200170, 0404000, 1200170, 0112101

FOGARTY INTERNATIONAL CENTER

The Norwegian Research Council for Science and the Humanities (NAVF) provides a limited number of research fellowships to U.S. health scientists to conduct research in Norway. The purpose of these fellowships is to enhance the exchange of research experience and information in the biomedical and behavioral sciences. The types of activity that are supported by this program include collaboration in basic or clinical research, and the familiarization with or utilization of special techniques and equipment not otherwise available to the applicant. The program does not provide support for activities which have as their principal purpose brief observational visits, attendance at scientific meetings, or independent study.

The program is administered for the NAVF by the Fogarty International Center (FIC), National Institutes of Health (NIH).

I. ELIGIBILITY

Applicants for the program must meet the following requirements:

1. U.S. citizenship or permanent U.S. residency;
2. a doctorate in a biomedical, clinical, or behavioral science;
3. 10 years or less of postdoctoral experience; and
4. professional experience in the health sciences for at least 2 of the last 4 years.

II. SUPPORT

The NAVF will provide the following support:

1. Stipends - Stipends are between N.kr 125,000 and N.kr 165,000 per annum.* The appropriate level for an individual fellowship is determined by the number of years of relevant or professional postdoctoral experience at the time of award. Professional experience such as teaching, internship, and residency may be considered relevant experience. Fellows may accept sabbatical salary, concurrent royalties, or other income from past services if reported in the application.

* Equivalent to approximately $16,000 - $22,000 per annum as of March 1984.

2. Travel - Round-trip air fare, tourist class, expenses are provided for the fellow only between the point of origin in the United States and the Norwegian host institution.

3. Health insurance - Health and accident insurance coverage are provided for fellows and accompanying family members during their stay in Norway. For the fellow, health and accident insurance are provided in transit to Norway. Fellows are strongly urged to purchase insurance in the United States to cover the round-trip transit period for accompanying family members.

III. DURATION OF PARTICIPATION

Fellowships are awarded for a 1 year period, but exceptions may be considered if recommended by the host institution and approved by the NAVF. The starting date of the fellowship is set by mutual agreement of the applicant and the institution, provided it is within the 10-month period immediately following the date of the award.

IV. APPLICATION AND SELECTION

Information and application forms are provided by the FIC. In addition to biodata and reference reports, the applicant will be required to include a clear and explicit description of the proposed activity to be carried out in Norway and the benefits expected from the experience. It is the applicant's responsibility to arrange for his or her research program with the sponsor in Norway either through direct correspondence or through correspondence in the applicant's behalf by a senior scientist in the United States with a Norwegian colleague. The sponsor's portion of the application should reflect that he or she is prepared to guide and administer the proposed research project, and can provide the necessary facilities.

The receipt date for applications at the FIC is October 1. Applications are reviewed for scientific merit by the NIH and are transmitted to the NAVF for final selection by the Medical Research Council. The selection meeting is held in June of the year following the receipt of applications. Shortly after the selection meeting candidates will be notified of the results by the NAVF.

V. INQUIRIES AND APPLICATION KITS

Chief, International Research and Awards Branch
Fogarty International Center
Building 38A - Room 613
National Institutes of Health
Bethesda, Maryland 20205

ANNOUNCEMENT

PSYCHODYNAMIC TREATMENT OF NONPSYCHOTIC DISORDERS

P.T. 34; K.W. 0414004, 0414013, 0415000, 0701029, 1201160, 1201170

NATIONAL INSTITUTE OF MENTAL HEALTH

I. PROGRAM SPECIFICATIONS

A. Program Objectives

The objective of this special announcement is to encourage and stimulate research on the evaluation of short-term or long-term psychodynamic psychotherapy with chronic or severe nonpsychotic disorders. A second objective is to stimulate the development and refinement of methods and instruments for the evaluation of process and outcome of psychodynamic psychotherapy. For purposes of this announcement, psychodynamic psychotherapy refers to a broadly defined class of psychotherapies whose theoretical basis clearly lies within the psychoanalytic tradition. The common goal in all psychodynamic therapies is insight. Primarily through the therapist's interpretation of the patient's in-therapy behavior in the context of his or her relationship with the therapist, a patient acquires insight into his or her interpersonal conflicts whose origins and recurrent enactments lie beyond the patient's awareness. These transferential reenactments of earlier consolidated patterns of conflictual interpersonal relationships are considered critical to the appearance of insight in therapy and therefore change in the patient. Transference phenomena are therefore assumed to mediate change in the patient's underlying core conflicts which are the presumed causes of the patient's symptomatology.

Nonpsychotic disorders, for purposes of this announcement, refer to those listed in the DSM-III. Particular interest centers on the anxiety and somatoform disorders, but the applicant is free to consider the full range of nonpsychotic disorders covered in the DSM-III. It is recognized that the DSM-III presents certain difficulties for diagnosing the kinds of chronic, interpersonal disorders that are particularly amenable to treatment by psychodynamic therapies. Axis I syndromic diagnoses are not adequate in themselves, while Axis II personality disorders thus far have been found to be unreliable. A combined diagnosis involving an Axis I syndromic diagnosis and an Axis II personality disorder diagnosis recently has been suggested as an appropriate compromise between the requirements of DSM-III and the particular emphases and foci of psychodynamic therapy. The applicant, however, need not be restricted to this suggestion.

B. Research Areas of Interest

Research grant applications are sought for the following kinds of efficacy and method development studies:

1. Efficacy Studies of Psychodynamic Psychotherapy

- o Pilot studies evaluating the efficacy of short-term, time-limited, and long-term forms of psychodynamic therapy. There are a few existing systematic empirical studies demonstrating the efficacy of psychodynamic therapy with any disorder. Preliminary pilot studies need to be conducted establishing initial effects. These studies should include follow-up assessments that would evaluate the durability of these effects associated with psychodynamic therapy. These pilot studies may involve intensive longitudinal designs or treatment/no-treatment comparisons applied to the same homogeneous diagnostic category.

- o Pilot studies indicating the efficacy of short-term or time-limited versus long-term forms of psychodynamic therapy. In recent years, several different forms of short-term and time-limited psychodynamic therapy have been developed which from the practicing clinician's point of view appear to be quite promising. But few controlled evaluations have been undertaken. It is therefore important to obtain data on several issues relating to the evaluation of their efficacy. First it is necessary to conduct pilot studies comparing short-term and time-limited therapy with no-treatment. Once their general efficacy in relation to no-treatment has been established, the renewal phase of this research would be the appropriate time to study whether short-term therapy can produce as much or more change than long-term psychodynamic psychotherapy applied to the same diagnostic grouping of patients. Process studies attempting to elucidate the basic mechanisms of effective short-term or time-limited therapy would follow.

- o Pilot studies of psychodynamic versus nonpsychodynamic psychotherapy. Initial pilot studies may also be considered comparing psychodynamic and nonpsychodynamic forms of psychotherapy. These comparisons may involve short-term, time-limited, or long-term therapy.

- o Pilot studies of patients characteristics predicting success and failure in psychodynamic psychotherapy. Most therapies are found to be efficacious for a limited subset of patients in a particular diagnostic category. Pilot studies are needed to determine for which subtypes of a given diagnostic category psychodynamic therapy is effective.

2. Method Development Studies

The greatest stumbling block to progress in research on psychodynamic therapy is the relative paucity of reliable and valid measures to assess the key constructs in psychodynamic therapy theory. The conduct of a scientifically valid clinical trial designed to evaluate the efficacy of psychodynamic therapy is predicted on the development of these reliable and valid measures. It is believed, however, that the best strategy for undertaking the development of these measures is to carry out this work within the context of the preliminary outcome studies mentioned above. Applicants are therefore encouraged to include, as an integral part of their efficacy study research proposals, plans for measurement development. This recommendation is not meant to exclude those applicants who may be interested in applying for modest research funds primarily in order to develop or refine a particular instrument or measure. Several areas have been identified as being in particular need of measurement development.

- o Measures of the core interpersonal conflicts. Reliable and valid measures are needed to identify the core interpersonal conflicts that presumably underlie a patient's psychopathology. Particular attention should be paid to the fact that underlying core conflicts represent a continuous variable and thus a determination must be made as to how much conflict is enough to require therapy and a diagnosis of severe psychopathology. Measures will need to be sensitive enough to identify the conflicts, establish that they are significantly interfering with or dominating a patient's life, identify the conditions either intrinsic or extrinsic that may be contributing to why the conflict is becoming a problem at this time, and determine the degree of penetrance that these conflicts have into other areas of the patient's functioning (e.g., work functioning, social functioning, degree of physical health disturbances). These measures should be able to detect changes in the various core conflicts.

- o Measures of repetitive maladaptive interpersonal patterns. Reliable and valid measures are needed to identify the repetitive maladaptive interpersonal patterns that presumably result from the patient's core conflicts. These patterns may be exhibited both within and outside the therapy session. Attention must be paid to the same considerations that are obtain with measures of core conflicts.

- o Measures of transference phenomena. In many, if not most, versions of psychodynamic therapy, a major mediator of therapeutic change involves the transference relationship that the patient develops with the therapist. It has been hypothesized that it is through the evocation and analysis of the transference relationship that patients in dynamic therapy eventually gain insight into their repetitive scenarios and core conflicts. Currently there are a few established measures which identify the appearance of transference phenomena, indicate changes in the

transference relationship, and/or specify the relationship between changes in the transference relationship and therapy outcome.

- o Measures of therapeutic alliance. Continued work is required on the further development and refinement of existing measures on the therapeutic alliance. The therapeutic alliance also has been hypothesized to be a critical element in the psychodynamic therapy process.
- o Measures of interpersonal change. Research is needed on the development of change along various interpersonal dimensions. Interpersonal variables are of particular significance to psychodynamic therapy; therefore, the development of measures which are sensitive to changes in the interpersonal domain may reveal the special potential of psychodynamic therapies.

- o Measures of therapeutic skill in conducting psychodynamic therapy. Research is needed on the development of reliable and valid measures of therapeutic skill in conducting dynamic therapy. Such measures are necessary in order to distinguish poorly conducted from competently conducted psychodynamic therapy.

II. CONSULTATION AND FURTHER INFORMATION

Preapplication consultation can be obtained from:

National Institute of Mental Health

Barry E. Wolfe, Ph.D.
Assistant Chief
Psychosocial Treatments Research Branch
Division of Extramural Research Programs
Parklawn Building - Room 10C-05
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: (301) 443-4527

III. APPLICATION RECEIPT AND REVIEW SCHEDULE

Receipt of Applications	Initial Review	Advisory Coucil Review	Earliest Award Date
July 1, 1984	Oct/Nov. 1984	February 1985	April 1, 1985

Applications will be reviewed for scientific merit by a peer review group consisting primarily of non-Federal experts. Applications will receive a secondary review for scientific/technical merit and policy consideration by the National Advisory Mental Health Council (NAMHC). Notification of review outcome will be sent to the applicant by the National Institute of Mental Health (NIMH). Only applications recommended for approval by the NAMHC can be considered for funding.

IV. REVIEW CRITERIA

Criteria for scientific/technical merit review of applications will include the following:

- Potential contributions to the field in areas covered by the objectives and scope of this special announcement.
- Adequacy of the conceptual and theoretical framework for the research.
- Evidence of familiarity with relevant clinical research literature.
- Scientific merit of the research design, approaches, and methodology.
- Adequacy of the data analysis plan.
- Qualifications and experience of the investigative team.
- Adequacy of the existing and proposed facilities and resources.
- Appropriateness of the budget, staffing plan, and time frame to complete the project.
- Adequacy of proposed procedures for protecting human subjects.

V. AWARD CRITERIA

The following criteria will be used in deciding to make an award for an application which has been recommended for approval:

- Quality of the proposed project as determined during the review process.
- Programmatic relevance of the proposed project.
- Availability of funds.

VI. TERMS AND CONDITIONS OF SUPPORT

Grants will be administered in accordance with the PHS Grants Policy Statement* including the policy regarding cost sharing.

VII. AVAILABILITY OF FUNDS

Applications received under this announcement will be considered for funding in Fiscal Year 1985. It is estimated that up to $500,000 will be available for approximately 5 to 8 new awards.

VIII. PERIOD OF SUPPORT

Applications may request support for up to 5 years; however, the typical period of support for pilot studies is expected to be 3 years. Applications for future submission deadlines are encouraged and will be considered under the regular program.

Public Health Service Grants Policy Statement, DHHS Publication No. (OASH) 82-50-000 GPO-017-020-0090-1 (rev.) December 1, 1982, available for $5.00 from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 10402.

☆ U.S. GOVERNMENT PRINTING OFFICE: 1984-421-144:1

NIH Guide
for Grants and Contracts

U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES

Vol. 13, No. 5, April 5, 1984

SPECIAL EDITION

LABORATORY ANIMAL WELFARE

The NIH Guide is published at irregular intervals to announce scientific initiatives and to provide policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in grants and contracts activities administered by the National Institutes of Health.

Two types of supplements are published by the respective awarding units. Those printed on yellow paper concern contracts: solicitations of sources and announcement of availability of requests for proposals. Those printed on blue paper concern invitations for grant applications in well-defined scientific areas to accomplish specific program purposes.

Have You Moved?
If you present address differs from that shown on the address label, please send your new address to: Grants and Contract Guide Distribution Center, National Institutes of Health, Room B3BN10, Building 31, Bethesda, Maryland 20205, and attach your address label to your letter. Prompt notice of your change of address will prevent your name from being removed from our mailing list.

RELEASE OF ANIMAL WELFARE REPORT

On several occasions over the past two years, the National Institutes of Health (NIH) published notices about its plan to conduct site visits to awardee institutions to determine the adequacy of its present assurance system for promoting the proper care and use of animals in biomedical research. The Office of Extramural Research and Training (OERT) completed its formal assessment in late 1983. The results of a series of site visits to ten awardee institutions are presented in the accompanying report, **SITE VISITS TO ANIMAL CARE FACILITIES: A Report to the Director of the National Institutes of Health, March 1984.**

The report concludes that reliance on the present NIH policy of voluntary compliance with the provisions of the Animal Welfare Act and NIH policy outlined in the Guide for the Care and Use of Laboratory Animals is an effective way to foster the welfare of laboratory animals. At the same time, the site visits proved very informative and suggested ways by which the NIH might make its assurance process even more effective. One major recommendation is to expand and strengthen the Public Health Service (PHS) Policy on laboratory animals.

Although institutions and research investigators have the primary responsibility for the proper care and use of animals in PHS-funded projects, the Office for the Protection from Research Risks (OPRR), NIH, is responsible for the general administration and policy. No PHS awards involving animals or animal facilities are made unless an acceptable written assurance statement is on file with the OPRR, NIH.

During the past year, the OPRR has given the PHS policy careful review and is now prepared to make its latest (March 1984) draft revision, PUBLIC HEALTH SERVICE, POLICY ON HUMANE CARE AND USE OF ANIMALS BY AWARDEE INSTITUTIONS, available for comment by the biomedical community and the general public. The Policy reflects several changes in policy and procedures, some suggested as a result of the recent series of site visits.

Because of intense interest in these recent initiatives, we have decided to publish these related documents in a special edition of the NIH Guide for Grants and Contracts. The NIH, as a steward of public funds, has been mindful about public concerns about animal experimentation and continues to make vigorous efforts on behalf of animal welfare. This OERT site visit report and the draft revised PHS Policy are the products of activities directed toward ensuring the welfare of research animals.

William F. Raub, Ph.D.
Deputy Director for Extramural
Research and Training
National Institutes of Health

SITE VISITS TO ANIMAL CARE FACILITIES

A Report to the Director of the National Institutes of Health
March 1984

I. INTRODUCTION

This report summarizes the results of a series of site visits to ten randomly selected institutions that receive funds from the National Institutes of Health (NIH) for research projects involving animals. The objective of this survey was to determine whether these awardees' programs and facilities for the care and use of laboratory animals are consonant with their statements of assurance now on file with the NIH. Such information is indispensable for assessing the adequacy of administrative requirements and practices in this area on the part of both the NIH and the awardee community.

II. BACKGROUND

As a part of its overall mission to improve human health through biomedical research, the NIH recognizes its obligation to promote appropriate care and use of animals involved in research. It is the policy of the NIH that no research award be made unless a responsible official of the institution that proposes to use the animals has provided an acceptable written assurance to the Office for Protection from Research Risks (OPRR), NIH. The assurance commits the institution to comply with the Animal Welfare Act of 1966, as amended; other applicable laws and regulations; the NIH Principles for the Use of Animals, as stated in the Public Health Service (PHS) policy; and the Guide for the Care and Use of Laboratory Animals (hereafter referred to as the Guide).

In demonstrating conformance to this assurance, awardee institutions are required, according to the provisions of PHS policy, to appoint and maintain animal care committes with authority and responsibility to inspect animal facilities at least annually and to oversee the care and use of animals at that institution. As required by PHS policy, such local committees must be composed of at least five members with relevant scientific expertise, including at least one veterinarian. Under current policy, institutions must choose one of the following three options: (1) accreditation by the American Association for Accreditation of Laboratory Animal Care (AAALAC); (2) self-accreditation indicating full compliance with the Guide; (3) self-accreditation indicating less than full compliance with the Guide and the efforts underway to remedy the deficiencies.

As a matter of policy, the NIH negotiates assurance statements carefully but makes no systematic effort to assess compliance unless concerns are raised by the following: (a) initial review groups--advisory panels composed of non-federal experts who are required to review proposals and applications for scientific merit and who are knowledgeable of the appropriateness of the species and numbers of animals required for a particular project; (b) NIH staff involved in reviewing requests for funds or administering actual awards; (c) authorized inspections such

as those performed by the United States Department of Agriculture (USDA); and/or (d) individuals or groups who submit evaluable allegations. In recent years, critics of NIH policies have questioned the adequacy of the assurance process, both in concept and in relation to specific instances of actual or apparent failure by awardee scientists or administrators to follow certain animal care practices. Because of the need to maintain public confidence in science and the individuals to whom federal funds are entrusted, the NIH decided to assess the adequacy of its traditional assurance system.

Under the leadership of the NIH Office of Extramural Research and Training (OERT), teams composed of Government and non-Government scientists conducted site visits to a stratified random sample of ten awardee institutions to gather information and impressions relevant to the following questions: Is the NIH's current assurance system adequate for promoting the proper care and use of animals involved in federally-funded biomedical research? If it is adequate, how it can be further improved? If it is not adequate, what alternatives should be considered?

Although the results of ten visits cannot provide a definitive assessment of the assurance system--there are more than 800 institutional assurances on file with the OPRR, NIH--the findings reported herein are not only a major step toward answering these questions but also an important interim aid to the NIH and the research-oriented institutions with which it deals.

III. METHODS

In order to carry out the proposed site visits, the NIH Director and the Institute, Bureau and Division (BID) Directors asked the NIH Deputy Director for Extramural Research and Training (DDERT). Dr. William F. Raub, to organize an internal advisory group made up of representatives of the various NIH components responsible for animal welfare. The committee was responsible for guiding the overall project. Dr. Raub appointed Dr. Louis R. Sibal of his Office to devise a protocol for conducting the visits and to act as the chairperson for the assessment teams. In January and February 1983, NIH officials tested the protocol by conducting visits to three AAALAC-accredited institutions near the Washington, DC area. The purpose of these visits was to determine whether the protocol would provide the information necessary for assessing the assurance system.

In February 1983, the NIH published a notice that the site visits would be made to a stratified, random sample of ten institutions that do not have accreditation from AAALAC but operate under approved assurances indicating full compliance with the Guide. The institutions were selected such that (a) one institution was chosen from each of the ten geographic regions of the Department of Health and Human Services (DHHS), and (b) the ten institutions were distributed among three categories of total annual NIH support as follows: more than $10 million (3), $5-10 million (3), and less than $5 million (4).

In June of 1983, the NIH published a notice of its intention to conduct site visits to the following institutions between June and September, 1983:

DHHS REGION	INSTITUTION/LOCATION
1	Brandeis University, Waltham, MA
2	New York University, New York, NY
3	Children's Hospital of Pittsburgh, Pittsburgh, PA
4	Bethune-Cookman College, Daytona Beach, FL
5	Northwestern University, Evanston, IL
6	University of Texas-Austin, Austin, TX
7	St. Louis University, St. Louis, MO
8	LDS Hospital, Salt Lake City, UT
9	Syntex Research Division, Palo Alto, CA
10	University of Washington*, Seattle, WA

In general, the protocol for the visits was designed to determine: (1) the administration's commitment to implementing the institutional policies governing research with experimental animals; (2) the animal care committee's role and responsibilities for oversight activities; (3) the investigator's understanding of proper animal care procedures; (4) the veterinarians' responsibilities for the management of laboratory animal facilities as well as animal care and use; and (5) the condition and design of the animal care facilities as an important element of good animal care.

Once the NIH approach to conducting the site visits had been refined, OERT obtained the services of a contractor (HCR, Washington, DC) to provide logistical aid for implementing the project. The NIH chairperson notified the appropriate institutional representative(s) at least one month before the scheduled visit and directed the contractor to collect and distribute background information from the institutions for site visit team members and arrange for reimbursement of the travel and subsistence expenses of the consultants.

Depending on the size of the institution and the complexity of its physical facilities, the teams were comprised of three to seven members led by the NIH chairperson. At a minimum, the site visit teams consisted of (a) a veterinarian, (b) a biological scientist currently working with animals and (c) an NIH scientist/administrator. Non-federal consultants were included with a view toward ensuring impartiality and enhancing expertise. Some consultants were selected because they had participated in or chaired NIH review committees (study sections) or institutional review committees (animal care committees), or because they had professional qualifications and experience in directing animal care programs. Most of the veterinarians had participated on AAALAC review

* At the time of selection, the NIH had not been notified of this institution's AAALAC accreditation.

teams. All of the site visitors had an ongoing interest in animal care and use; most were well-qualified by their training and experience in conducting research involving laboratory animals. In the interests of economy, consultants were often recruited from the geographic region of the institution to be visited; some were asked to serve on two visits, thereby reducing the total pool of persons required for the project.

In all but three instances, the site visits were performed in one day; two days were allotted for visits to larger institutions with multicentered animal care facilities. Prior to the visit the contractor sent each team member background information, which included the written statement of assurance on file with the OPRR, USDA inspection reports, handbooks, and minutes or reports of meetings of institutional officials and of animal care committees. The NIH chairperson conducted an on-site orientation session before each visit to ensure that team members understood the objective of the visit. At the completion of the visit, site visitors shared their assessments orally with institutional officials, indicating any major strengths and weaknesses of the animal care program.

IV. FINDINGS

The site visits were designed so that each institution's mechanisms for complying with its statement of assurance could be evaluated at every level of participation. In addition to inspecting facilities and questioning laboratory animal care personnel, the site visit teams asked institutional officials fundamental questions about how they organize and maintain oversight of animal research. Administrators and scientists with whom the site visitors spoke for the most part were supportive of the NIH's efforts to assess its assurance system and welcomed the opportunity to comment on their own programs. The comments from institutional officials and staffs were responsive and candid.

This section is subdivided into five parts summarizing the findings concerning administrative support, animal care committees, investigators, veterinary care and animal research facilities.

A. Administrative Support

One of the goals of the site visits was to evaluate the nature and extent of support given by administrative officials to laboratory animal programs. At each institution, the administration was usually represented by the most senior administrative official responsible for research conducted at the institution. This official was generally the person who signed the assurance document submitted to OPRR. Representation ranged from university vice-presidents and hospital administrators to deans or assistant deans of schools, as well as business and financial officials. Site visitors asked these officials to describe how oversight of animal facilities and research involving animals is maintained and how their current procedures ensure compliance with PHS policy and with the Guide.

At each institution visited, administrators demonstrated adequate understanding of and support for the operation of a laboratory animal program. Depending on the size of the institution, officials described organizations for maintaining centralized control over the care and use of

laboratory animals. Most officials actively participated in planning programs to provide animals and animal care essential to high-quality research and had designated at least one person as a director of laboratory animal care.

While a variety of oversight procedures were identified, programs for monitoring compliance were generally accomplished by:

- Establishing institutional policies governing research involving animals based on (a) specific knowledge of the needs of animals, (b) requirements for the research, and (c) conformance with Federal regulations and guidelines;

- Developing an organizational plan in which the animal care committee and animal care director are directly responsible to a senior administrative official;

- Establishing a strong central authority for (a) the procurement of animals, caging and/or housing systems, food and other supplies; (b) hiring of professional and technical support personnel, including employee training, education and health programs; and (c) veterinary services;

- Maintaining a central animal facility with financial accountability, usually with established user fees, per diem charges and other defined costs;

- Subsidizing the animal research program by (a) providing the salaries of professional and support staff; (b) purchasing capital equipment; and (c) maintaining, upgrading, renovating and constructing animal care facilities, laboratories and special procedures rooms.

In all but one of the ten institutions visited, administrators described some combination of these kinds of financial and programmatic procedures.

On many of the visits, administrative officials and staffs discussed the possibility of their institutions seeking AAALAC accreditation. The administrators acknowledged that this system of accreditation is accepted by the scientific community and by the concerned public.

On three occasions site visitors found that some laboratory animals were not actually housed at the awardee institution. Instead, they were maintained at a neighboring institution. While the actual research site might have been stated in the application or proposal, it was not recorded in the statement of assurance. The visitors had no cause to believe that the welfare of the animals was being compromised, but they were concerned that, lacking formal access to the other institution, it might be difficult for the awardee institution to exercise its oversight responsibilities.

B. Animal Care Committees

The site visitors spent a substantial amount of time with animal care committee members to determine the effectiveness of these bodies. The

membership of the committee was generally representative of the community of users of research animals. The chairperson reported directly to the senior institutional official, in most instances the individual signing the statement of assurance. With some exceptions, the chairperson was highly knowledgeable of animal welfare issues and respected as a good leader. In every case, at least one of the committee members was a veterinarian. A few institutions had appointed a lay person to serve on the committee. Meeting first with the chairperson and then with the entire committee, site visitors asked members about their role and their overall level of involvement and interaction with administrative officials, fellow scientists, veterinary staff and animal care personnel.

Committee members saw their role as ensuring that optimal conditions for research are maintained in animal facilities. Institutional committees generally described themselves as having assumed some or all of the following responsibilities:

- Working with administrators and veterinarians to oversee the operation of animal care facilities by (a) conducting periodic inspections of animal care facilities, (b) setting or approving per diem charges, (c) allocating space, (d) orienting new faculty/staff members on standard procedures of operation, and (e) developing guidelines for hiring, training and promoting animal care personnel;

- Reviewing at least some of the institution's research protocols involving laboratory animals for (a) appropriateness of numbers and species of animals used, and (b) the appropriateness of the procedures to be performed on living animals in relation to benefits gained from advancing scientific knowledge;

- Reviewing with special emphasis those procedures that may cause discomfort and/or pain to animals as well as methods used to alleviate any distress to animals such as suitable anesthesia or analgesia;

- Providing competent scientific advice to administrators on matters relating to (a) institutional animal welfare policies and practices; (b) animal welfare legislation, both local and national; and (c) biomedical research using experimental models other than vertebrate animals.

The site visitors found that the animal care committees were generally not as active as their charters (organizational descriptions) had depicted them: some of the stated responsibilities were not addressed on a regular basis; all or part of the review functions were often delegated to the veterinarian, chairperson, and/or administrative staff, or they were performed in a routine manner.

Further discussion brought out the fact that animal care committee members (and other scientists within the institution) sometimes placed too much reliance upon NIH scientific review groups to evaluate research involving laboratory animals. Institutional officials and staffs were aware that, according to PHS policy, consultants participating on NIH study

sections and on-site visits are expected not only to review research applications for scientific merit but also to evaluate experimental procedures involving laboratory animals.

For the most part, the site visitors were convinced that animal care committees recognized and took action to correct inappropriate experimental procedures involving laboratory animals and/or problems related to the operation of the animal care facilities, even if each issue did not always receive the benefit of group discussion. The reasons given for delegating the responsibility of protocol review and for management of the animal facility varied. In most instances, animal care committee members indicated that veterinarians were in the best position to evaluate protocols for deviations from appropriate practices and to monitor animal care, allowing the committee to concentrate on other issues.

The site visitors discussed the possibility of appointing an individual who is not a scientist and/or not affiliated with the institution to the committee. Two of the committees already included non-affiliated lay persons. These individuals had been selected because of their community standing, concern for animal welfare and their understanding of the need to use animals in biomedical research. Their participation on animal care committees was considered extremely useful because they provided different perspectives on issues dealing with animal care and use. Officials of institutions whose animal care committees did not include a lay member generally favored considering such an appointment.

C. Investigators

At each institution, the site teams spoke with faculty/staff scientists to evaluate their role in maintaining compliance with the Guide. In advance of each visit, OERT used the NIH data system to select a list of investigators from representative departments and areas of study. Investigators were asked to describe their own work, available veterinary care, recordkeeping, training, their interaction with the animal care committee, technicians and caretakers, and the quality of animal care provided at their facility.

For the most part, those interviewed understood the NIH assurance system and appeared to take compliance issues seriously. They were familiar with and supportive of the oversight procedures, such as the review of research proposals, allocation of space in the animal facilities, ordering and purchasing animals and supplies, and standard operating procedures in effect at their institutions.

These scientists were generally familiar with the activities of the animal care committee and understood its function. They routinely addressed concerns about the management of the facility, planning, costs and care to the committee. Some investigators related instances when they had been asked by committee members to provide more information for the review of their protocols. A few indicated that they had been advised to modify an experimental procedure involving animals. Most investigators were familiar with the Guide, even though they were not always thoroughly knowledgeable of its contents. Investigators working in central animal facilities generally used the wide variety of veterinary services available to them. They related

instances when they sought advice and/or assistance from the animal care director in developing animal models, designing equipment and/or caging, performing procedures, screening for disease and solving disease problems in their animal colonies.

Investigators working at sites remote from the central facilities seldom had access to staff technicians and caretakers; their contact with veterinarians and veterinary personnel was often limited to brief periods during routine inspections. In some institutions of higher education, undergraduate and post graduate students from the biological or behavioral sciences often performed procedures which, in the central facility, were performed by animal care personnel. These students worked under the direct supervision of a professional scientist. In discussing the reasons for continuing these practices in satellite laboratories, the scientists explained that: (a) the central facility was not readily accessible; (b) departmental laboratories were designed and maintained properly to meet the specific needs of a research program involving animals; or (c) the costs of the central animal facility were too high. However, investigators citing prohibitive costs did not always know how animal per diem rates and user fees were derived.

D. Veterinary Care

The site visit teams found that meetings with veterinarians were extremely helpful in assessing animal care practices at institutions large enough to support at least one full-time veterinarian. Present during most of the interviews and laboratory visits, the staff veterinarian was able to answer many questions about current institutional policies and future plans. Frank discussions among veterinarians and members of the site visit teams often helped to correct any misconceptions about animal care programs.

The role of the veterinarian depended on the size and scope of the scientific program at the institution but almost invariably was a pivotal one in the oversight of biomedical research involving animals. In addition to providing service to the institution's animal facility, some veterinarians had departmental appointments with teaching assignments and research activities. Most had developed comprehensive centralized animal care services. In the larger institutions, a well-trained support staff purchased animals, feed, caging and other supplies and maintained financial accountability through effective information and recordkeeping systems. Some veterinarians were delegated full responsibility for conducting the primary review of proposed research protocols involving animals. As noted previously, animal care committees relied heavily on the advice and professional judgment of the veterinarian in reviewing experimental protocols, especially with respect to conformance to PHS policy and the Guide.

Veterinarians or their staffs usually maintained a close working relationship with investigators and assisted them on such matters as animal husbandry, animal biology, animal disease and experimental surgery. Veterinarians interacted with the administrators, animal care committee members and staff scientists in meeting their responsibilities. Scientists at most of the sites credited the veterinarian(s) with improving the conditions for animal

research at their institution. However, a few appeared to be limited in their effectiveness because they were overburdened by numerous administrative responsibilities or were not provided sufficient support staff to cover large, diffuse facilities.

Veterinarians at smaller institutions worked under a contract or on a fee-for-service basis. Depending on the complexity of the programs, they routinely inspected animal care facilities, participated in animal care committee meetings and advised institutional scientists on matters relating to the general health of laboratory animals and on the appropriateness of experimental procedures involving animals, provided preventive care as appropriate, and attended sick animals.

E. Animal Facilities

The site visitors inspected the premises where animals are bred, maintained and treated. Even when the facilities were extensive, team members were able to assess most of the areas within central and satellite laboratories, including storage, cage sanitation, special procedures and surgical rooms. Based on their professional experience and judgment, they evaluated the general condition of the physical plant, observed the quality of animal husbandry, recordkeeping, caging, and sanitation and appraised the overall health of the laboratory animals. During the visits, the members questioned veterinarians, technicians and caretakers about standard and emergency operating procedures of the animal facility.

In inspecting the environment of the laboratory animals, the site visit team found no conditions that might violate the Guide at the ten institutions. Other than for minor deficiencies in the physical plants, the centralized facilities were usually adequate to excellent. Even in the older facilities, the animal areas were clean and well-organized, with little or no overcrowding. There was proper concern for access to food and water. Animals were comfortably caged and appeared healthy.

Because the site visitors learned that certain procedures involving animals were performed in satellite facilities in some institutions, they made special effort to visit as many of them as practicable. In a few instances, they were invited by scientists to observe experiments in progress. Visits to satellite facilities, which are defined in this report as any building, room, area, or vehicle designed to confine, transport, maintain, treat or use animals not within the central facility, were not usually announced in advance and took place during the general evaluation of the institution's central facilities. Conditions in some satellite animal facilities were inadequate. Although they represented only a small percentage of animal care space, the satellite facilities were more likely to be crowded, with less control over environmental conditions, e.g., heat, light. Veterinary services and monitoring of the animals housed outside the central facility tended to be less than comprehensive.

In general, laboratory animal technicians and caretakers working in central facilities have been trained in programs offered by the American Association of Laboratory Animal Science. Technicians in most institutions were encouraged to seek advanced training and certification for promotions to more responsible, higher-paying positions.

V. CONCLUSIONS

Although there are necessary operational differences in the laboratory animal care programs among the ten sites selected for this study, it is clear that all institutions share a common concern--that the care and use of laboratory animals be in accord with good science and that the welfare of the animals be considered. We conclude:

1. Reliance upon voluntary compliance with PHS policy and recommendations in the Guide is a realistic approach to fostering proper care and use of laboratory animals in biomedical research. There is no reason to believe that regular NIH inspections are needed or would be more effective than the traditional assurance process.

2. The present assurance system should be strengthened by modifying the current PHS policy on animal welfare to promote more conscientious involvement by both the NIH and its awardee institutions.

These conclusions are based on the following findings:

- o No incidents of animal abuse were observed.

- o In general, senior administrative officials had accepted responsibility for the appropriate care and use of animals involved in PHS-funded projects by supporting effective animal care programs. Most of these officials: (a) possessed adequate knowledge of Federal animal welfare requirements; (b) provided financial support by subsidizing animal care personnel and animal care facilities; and (c) created strong centralized authority by linking an animal care director (veterinarian) and the animal care committee to the overall management plan.

- o In general, the institutional animal care committees met periodically to provide the senior administrative officials with advice and guidance on matters dealing with the proper care and use of animals in biomedical research. Although the committees differed widely in their procedures and responsibilities, most were chaired by a highly knowledgeable leader and served by competent member scientists who were representative of the research community within the institution. Given these capabilities, the site visitors were disappointed to find that the animal care committees frequently seemed less than fully assertive in exercising their responsibilities. Some suggestions for increasing the impact of these committees are addressed among the recommendations of this report.

- o At all institutions, most investigators interviewed understood or at least were familiar with institutional policies and procedures, and the PHS policy and Guide. Most demonstrated their willingness to work within the Federal and institutional animal care systems by: (a) submitting research protocols involving animals to institutional officials, the veterinarian, animal care committee chairperson and members, especially for procedures

that might cause pain or discomfort to experimental animals or require anesthesia or analgesia; (b) cooperating with periodic inspections of satellite facilities by the attending veterinarian and/or members of the animal care committee; and (c) heeding the advice of NIH scientific review groups with respect to the adequacy of the care and use of laboratory animals in biomedical research.

- At all institutions, a full- or part-time attending veterinarian had been appointed. In most cases, the attending veterinarian possessed advanced training in laboratory animal medicine. Senior administrative officials, scientists, and animal care committee members were heavily dependent on the knowledge and leadership of this individual for advising on matters of animal care, future planning, public service relations and keeping the facilities and programs at the institution in compliance with the Guide. The responsibilities of the animal care director varied among the institutions but often included: (a) operation of laboratory animal care program; (b) operation of the animal care facilities, especially the central facility if it existed; (c) oversight and concurrence on experimental procedures involving animals; and (d) monitoring of animal health both in central and satellite facilities.

- Most of the animal care directors provided dedicated and effective leadership of their animal care programs to the extent that they were given authority by the administration and were not overburdened with routine duties and responsibilities.

- In all of the institutions, the physical plant of the central animal facility was adequate to excellent; however, where satellite facilities existed, deficiencies were common and problems seemed more likely to occur.

VI. RECOMMENDATIONS

Notwithstanding the overall conclusions described above, the site visits proved instructive with respect to ways that the NIH and its awardees could make the system of voluntary compliance even more effective. These are as follows:

- The NIH should undertake a program for helping institutional officials, scientists and animal care directors (veterinarians) understand fully their responsibilities in implementing the PHS Policy on the Care and Use of Laboratory Animals. More specifically, institutional officials should know in detail what constitutes a successful program of laboratory animal care and how to structure one that ensures control over all animal care activities, especially those conducted in satellite facilities and at neighboring institutions.

- The PHS Policy on the Care and Use of Laboratory Animals should be expanded to include more specific information regarding responsibilities of the institution that receives funds for research involving the use of animals. These responsibilities

should be clearly described and incorporated in new animal welfare assurance statements to be negotiated with the OPRR, NIH. The OPRR should negotiate these assurances carefully and promptly. The information contained in the assurance document should be examined and updated periodically.

- The PHS policy should be further modified to define more precisely the responsibilities of the awardee institutions, particularly the role of the animal care committee. It is imperative that the experience and expertise of the members of such committees be used to conduct full and effective reviews of proposals involving research with animals. The appointment of a non-scientist and an individual unaffiliated with the institution should be given serious consideration.

- The NIH should consider conducting or sponsoring a survey to assess whether the number of veterinarians trained in laboratory animal science is sufficient to meet the needs of institutions conducting biomedical research involving animals.

- The NIH should conduct further assessment of the assurance process: in particular, the NIH should visit additional awardee institutions receiving total annual support of less than $5 million. The sample size should be increased because this category has the largest number of institutions with assurance statements on file with the OPRR.

PREAMBLE - PROPOSED PUBLIC HEALTH SERVICE POLICY ON HUMANE CARE AND USE OF ANIMALS BY AWARDEE INSTITUTIONS

The Public Health Service (PHS) is proposing to amend the PHS Extramural Animal Welfare Policy as specified in DHEW Grants Administration Manual Chapter 1-43, "Animal Welfare." This notice summarizes the proposed changes and includes the proposed policy, on which public comment is encouraged. Written comments on the proposed policy should be received on or before July 15, 1984 if they are to be given full consideration. Please send comments to the following:

Carol Young
Office for Protection from Research Risks
National Institutes of Health
9000 Rockville Pike
Building 31 - Room 4B09
Bethesda, Maryland 20205

In addition, PHS intends to hold three open hearings to give the public an opportunity to make oral comments on the proposed policy. The times and places of the hearings will be announced at a later date.

I. BACKGROUND

Responsibility for the humane care and use of animals involved in activities supported by grants or contracts from the PHS rests primarily with the institutions receiving the award. In order to provide for the adequate discharge of this responsibility, the PHS requires that institutions receiving awards for projects that involve animals provide an Animal Welfare Assurance, as specified in the PHS Animal Welfare Policy. A National Institutes of Health (NIH) policy was instituted in 1971, and the revision which went into effect in 1979 was broadened to include all PHS components. The Office for Protection from Research Risks (OPRR), NIH has continuing responsibility for implementing the PHS Policy.

As part of the PHS ongoing review and assessment of its programs and policies, and in response to recommendations from the Office of Extramural Research and Training (OERT), NIH, to the Director, NIH, the PHS has determined that the existing policy should be revised in order to strengthen the assurance mechanism on which the policy is based. The PHS believes that a revised policy should (1) require that institutions designate clear lines of authority and responsibility for those involved in animal care and use issues, (2) more clearly define the role and responsibilities of Animal Research Committees (ARC) (formerly Animal Care Committees), (3) require that assurances provide more specific information regarding an institution's program for the conduct of experiments involving animals, and (4) require ARCs to review and approve the proposed use of animals in individual grants and contracts to ensure compliance with the institution's assurance.

II. SPECIFIC PROPOSED CHANGES:

A. Animal Welfare Assurances

The proposed policy requires that the assurance be signed by a responsible institutional official who bears final responsibility for the institution's entire program of animal care and use. This individual must be a high-level institutional administrator who has the authority to make a commitment on behalf of the institution that the requirements of the policy will be met. This individual will also be responsible for certifying that the ARC has reviewed and approved individual grants and contracts. The proposal also requires that the institution designate in its assurance a veterinarian (or veterinarians) qualified in laboratory animal medicine who will be responsible for supervising the care, use, housing and feeding of all animals. The PHS believes that appropriate veterinary care must include a comprehensive program involving many aspects (nutrition, examinations, sanitation, feed, TB tests, etc.), and should be administered by a veterinarian with experience and expertise in laboratory animal medicine.

The present policy requires all institutions to state that they are "committed to comply with the Principles for the Use of Animals (Principles), the Guide for the Care and Use of Laboratory Animals (Guide), the provisions of the Animal Welfare Act, and other applicable laws and regulations." The language in the proposed policy is stronger because it requires all institutions to "accept the Principles as mandatory" and to state that the institution has "implemented the requirements of the Guide and is committed to implementing the recommendations of the Guide." Since the Principles are intended to ensure that research involving animals is conducted in a humane manner and in appropriate facilities, the PHS believes that institutions must accept them as mandatory requirements. Similarly, since the Guide contains few absolute requirements and many recommendations, institutions should provide assurance that they have implemented the requirements and are committed to implementing the recommendations contained in the Guide. The Principles remain virtually unchanged in the proposed policy because the PHS is discussing with other Federal agencies the possibility of developing federal-wide principles for the care and use of laboratory animals. In the event that such principles are developed, they may be inserted in the policy at a later date.

The present policy provides three options for institutions with Animal Welfare Assurances. The proposed policy offers two options: (1) full accreditation by the American Association for Accreditation of Laboratory Animal Care (AAALAC) or (2) self-assessment by the institution of its animal program and facilities. Institutions covered by Option 2 will be required to submit with the assurance, and annually thereafter, a report to OPRR. The proposed policy details specific information which must be included in these reports. The information in the reports is intended to provide OPRR with sufficient information to assess the institution's implementation of the recommendations in the Guide, and the institution's progress towards remedying any deficiencies. The proposed policy also states that institutions covered by Option 2 may be selected at random for site visits by PHS staff and advisors to assess the adequacy of compliance with their assurance.

Institutions that are fully accredited by AAALAC and therefore covered by Option 1 would not be required to submit annual reports to OPRR and would not be subject to random site visits by PHS, although they may be visited if questions are raised regarding the institution's compliance with the policy.

B. Animal Research Committees

The proposed policy requires that institutions establish an ARC and contains specific requirements for the membership of the ARC. The present policy requires that the committee have at least five members and at least one doctor of veterinary medicine. The proposal states that the committee include at least five members, but in addition, specifically requires that the committee include an individual unaffiliated with the institution, the attending veterinarian with appropriate qualifying expertise in laboratory animal medicine, a practicing scientist experienced in laboratory animal medicine, and a member whose primary vocation is in a nonscientific area.

C. Functions of the Animal Research Committee

The PHS believes that an active ARC is an essential element of a good institutional animal care and use program, and therefore the proposed revision includes substantially more detail than the current policy on the appropriate role and responsibilities of the ARC. The ARC must have oversight responsibility for an institution's animal program, including the conduct of research supported by specific grants and contracts. The ARC is also given the authority to terminate a research activity if it determines that the activity cannot be brought into compliance with the policy.

Another substantive addition in the proposed policy is the requirement that the ARC review and approve the care and use of animals as set forth in applications and proposals. The proposal specifies five categories of animal use in research which must be reviewed and approved by a majority of the members of the ARC. Animal use in research which does not fall into the five categories must also be reviewed, but the review may be conducted by the ARC chairperson, or by a qualified ARC member designated by the chairperson. The purpose of the ARC review of research applications and proposals is to ensure that the described care and use of animals are in compliance with the policy and the institution's assurance, not to review for "scientific merit."

The proposed policy also specifies that no award will be made by PHS unless the responsible institutional official has verified that the care and use of animals in the proposed research has received the appropriate ARC review and approval.

D. Information Required in Applications and Proposals Submitted to PHS. The proposed policy states that applications and proposals must contain a complete description of the proposed use of the animals. This is intended to incorporate requirements already imposed on applicants and is not intended to place additional burdens on applicants.

E. Recordkeeping

To ensure that institutions maintain appropriate records, the proposal contains specific recordkeeping requirements. In the event that PHS conducts a site visit at an institution, the records would assist the PHS in determining the effectiveness of an institution's animal program, and of the assurance mechanism in general.

F. Waiver

The proposed policy states that an institution may request a waiver of a provision or provisions of the policy. However, no waiver would be granted unless sufficient justification is provided to OPRR and approved in advance and in writing. In any event, such waivers would be granted only in exceptional circumstances.

PROPOSED

PUBLIC HEALTH SERVICE

POLICY ON HUMANE CARE AND USE OF ANIMALS

BY AWARDEE INSTITUTIONS

I. INTRODUCTION

It is the policy of the Public Health Service (PHS) that before an institution receives a PHS award involving the use of animals the institution shall submit an Animal Welfare Assurance, acceptable to the PHS[1], stating that the institution will meet the requirements detailed below in Part I and that the institution (a) accepts as mandatory the Principles for the Care and Use of Laboratory Animals (Principles), (b) has implemented the requirements of the Guide for the Care and Use of Laboratory Animals (Guide) and is committed to implementing the recommendations of the Guide, and (c) is complying and will continue to comply with the Animal Welfare Act and all other applicable Federal statutes and regulations. Institutions and research investigators have primary responsibility for the humane care and use of animals involved in PHS-funded projects. Where the proposed work involves animals, no award will be made to an institution unless a responsible official of the institution has submitted, on behalf of the institution, an Animal Welfare Assurance acceptable to the PHS. Similarly, no award will be made to an individual unless that individual is affiliated with an institution which holds an accepted Animal Welfare Assurance.

This policy is applicable to recipients of any PHS support for research, training, testing or other activities involving the use of animals, whether performed by the awardee institution or by any other institution. The PHS requires administrators and investigators of foreign institutions receiving PHS funds for research involving the use of animals to follow only the PHS Principles for the Care and Use of Laboratory Animals.

II. DEFINITIONS

A. Animal

Any live, vertebrate animal used or intended for use in research, experimentation, testing, training or related purposes. The current Guide (see definition below) does not include recommendations on facilities for cold-blooded animals; however, the Principles for the Care and Use of Laboratory

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[1] Assurances shall be submitted to the Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH), Department of Health and Human Services (DHHS). Bethesda, Maryland 20205.

Animals (see definition below) and this policy apply to all live vertebrates.

B. Animal Facility

Any building, room, area or vehicle designed or used to confine, transport, maintain or use animals, including satellite facilities. A satellite facility is any facility in which animals are housed for more than 24 hours outside the central facility.

C. Animal Welfare Act

Public Law 89-544, 1966, as amended, (P.L. 91-579 and P.L. 94-279) 7 U.S.C. 2131 et. seq. Implementing regulations are published in the Code of Federal Regulations (CFR), Title 9, Subchapter A, Parts 1, 2, 3 and 4, and are administered by the U.S. Department of Agriculture.

D. Assurance

Animal Welfare Assurance, the documentation on file wit (or submitted when requested by) the OPRR, from an awardee or a prospective awardee institution, assuring institutional compliance with this policy.

E. Guide

Guide for the Care and Use of Laboratory Animals, DHEW, NIH Pub. No. 78-23, 1978 edition or succeeding revised editions.

F. Institution

Any public or private institution, organization or agency (including Federal, state or local government agencies) in the United States, the Commonwealth of Puerto Rico, or any territory or possession of the United States.

G. Principles

Principles for the Care and Use of Laboratory Animals (see below).

H. Responsible Institutional Official

An individual who bears final responsibility for the entire program of animal care and use at the institution, and who has the authority to sign the institution's assurance and to make a commitment on behalf of the institution that the requirements of the PHS policy will be met.

III. PRINCIPLES FOR THE CARE AND USE OF LABORATORY ANIMALS

A. The Personnel

1. Experiments involving live, vertebrate animals and the procurement of tissues from living animals for research must be performed by, or under the immediate supervision of, a qualified biological, behavioral, or medical scientist.

2. The housing, care, and feeding of all experimental animals must be supervised by a properly qualified veterinarian.

B. The Research

1. The research should be such as to yield fruitful results for the good of society and not random or unnecessary in nature.

2. The experiment should be based on knowledge of the disease or problem under study and so designed that the anticipated results will justify its performance.

3. Statistical analysis, mathematical models, or in vitro biological systems should be used when appropriate to complement animal experiments and to reduce numbers of animals used.

4. The experiment should be conducted so as to avoid all unnecessary suffering and injury to the animals.

5. The scientist in charge of the experiment must be prepared to terminate it whenever he/she believes that its continuation may result in unnecessary injury or suffering to the animals.

6. If the experiment or procedure is likely to cause greater discomfort than that attending anesthetization, the animals must first be rendered incapable of perceiving pain and be maintained in that condition until the experiment or procedure is ended. The only exception to this guideline should be in those cases where the anesthetization would defeat the purpose of the experiment and data cannot be obtained by any other humane procedure. Such procedures must be carefully supervised by the principal investigator or other qualified senior scientist.

7. Post-experimental care of animals must be such as to minimize discomfort and the consequences of any disability resulting from the experiment, in accordance with acceptable practices in veterinary medicine.

8. If it is necessary to kill an experimental animal, this must be accomplished in a humane manner, i.e., in such a way as to ensure immediate death in accordance with procedures approved by an institutional committee.

C. The Facilities

1. Standards for the construction and use of housing, service, and surgical facilities should meet those described in the publication, Guide for the Care and Use of Laboratory Animals, DHEW No. 78-23 (reprinted in 1980 DHEW 80-23), or succeeding editions or as otherwise required by the U.S. Department of Agriculture regulations established under the terms of the Animal Welfare Act (P.L. 89-544) as amended.

D. Transportation

1. Transportation of animals must be in accord with applicable standards and regulations, especially those intended to reduce discomfort, stress to the animals, or spread of disease. All animals being received for use as experimental subjects and having arrived at the terminal of a common carrier must be picked up and delivered, uncrated, and placed in acceptable permanent facilities promptly.

IV. IMPLEMENTATION BY AWARDEES

Before an institution is eligible to receive PHS support for projects in which animals are to be involved, the institution must submit to the Office for Protection from Research Risks (OPRR), Office of the Director, National Institutes of Health, an Animal Welfare Assurance acceptable to OPRR, stating that the institution will meet the requirements detailed in this policy and that the institution

- accepts as mandatory the Principles for the Care and Use of Laboratory Animals (Principles),
- has implemented the requirements of the Guide for the Care and Use of Laboratory Animals (Guide) and is committed to implementing the recommendations of the Guide, and
- is complying and will continue to comply with the Animal Welfare Act and all other applicable Federal statutes and regulations.

This policy does not affect applicable state or local laws or regulations which impose more stringent standards for the care and use of laboratory animals.

A. Animal Welfare Assurance

The Animal Welfare Assurance (assurance) shall be typed on the institution's letterhead and signed by a responsible institutional official who has the authority to make a commitment on behalf of the institution and who bears final responsibility for the entire program of animal care and use at the institution. OPRR will provide the applicant institution with necessary definitions, instructions, and an example of an acceptable assurance. Subsequent to the institution's submission of an assurance, OPRR will notify the institution as to the acceptability of the assurance. No project proposing to use animals will be supported, and no active PHS project will be permitted to continue, in the absence of an acceptable assurance. Significant changes in the status of an existing assurance, departures from information submitted in an annual report (see Option 2), or problems encountered in implementing this policy shall be reported immediately to OPRR. After reviewing changes or problems, OPRR may require renegotiation of the assurance or other appropriate actions. In any case each institution must submit a new and complete assurance to OPRR at least every 5 years.

1. Program for Animal Care and Use

The assurance must contain a description of the institution's program for animal care and use, designating:

a. appropriate lines of authority and responsibility for administering the program and ensuring compliance with this policy; and

b. the veterinarian(s) qualified in laboratory animal medicine who will be responsible for supervising the housing, feeding, and care and use of all animals.

2. Institutional Status

The assurance must include a statement indicating that the institution has adopted one of the following options:

Option 1 - The institution is fully accredited by the American Association for Accreditation of Laboratory Animal Care (AAALAC) or other accrediting body recognized by PHS2 and (a) accepts as mandatory the Principles for the Care and Use of Laboratory Animals (Principles), (b) has implemented the requirements of the Guide for the Care and Use of Laboratory Animals (Guide) and is committed to implementing the recommendations of the Guide, and (c) is complying and will continue to comply with the Animal Welfare Act and all other applicable Federal statutes and regulations.

An institution may not adopt Option 1 unless the institution has received full accreditation, by AAALAC or other accrediting body recognized by PHS, for all of its programs and facilities, including satellite facilities. An institution that has received provisional or probationary accreditation, or whose accreditation is revoked or is currently being withheld for any of its facilities, including satellite facilities, must select Option 2.

Option 2 - The institution has conducted a self-assessment (as described in the institution's assurance and annual reports) and the institution (a) accepts as mandatory the Principles for the Care and Use of Laboratory Animals (Principles), (b) has implemented the requirements of the Guide for the Care and Use of Laboratory Animals (Guide) and is committed to implementing the recommendations of the Guide, and (c) is complying and will continue to comply with the Animal Welfare Act and all other applicable Federal statutes and regulations.

Institutions covered by Option 2 must submit with the assurance and thereafter annually a report to OPRR. These reports will become a part of the assurance. Failure to submit an annual report may result in withdrawal by OPRR of the acceptance of the assurance.

Each report shall contain, at a minimum:

(a) a description of the nature and extent of the institution's adherence to the Principles and to the requirements and recommendations contained in the Guide;

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2 As of March 1984, the only accrediting body recognized by PHS is the American Association for Accreditation of Laboratory Animal Care (AAALAC).

(b) a description of deficiencies, if any, in the institution's adherence to the requirements and recommendations contained in the Guide;

(c) a plan of action, including a specified time frame, for correcting deficiencies described in "(b)" above;

(d) progress towards remedying deficiencies previously described in "(b)" above; and

(e) the Animal Research Committee's recommendations for changes or improvements as forwarded to the responsible institutional official and other appropriate institutional officials (see B. Functions of the Animal Research Committee).

Upon consideration of the annual report and the institution's implementation of its assurance OPRR may impose specific restrictions or requirements pertaining to the care and use of laboratory animals.

3. Animal Research Committee (ARC)

Each institution shall appoint an Animal Research Committee (ARC), sufficiently qualified through the experience and expertise of its members to maintain oversight of the institution's animal program, facilities and procedures, and to provide complete and adequate review of research activities involving animals conducted by the institution.

The assurance must include the names, position titles and credentials of the ARC members, the ARC chairperson, and the responsible institutional official (see definitions). The membership of the ARC shall include:

a. at least five members;

b. at least one Doctor of Veterinary Medicine who is responsible for supervising the housing, feeding, and care and use of all animals at the institution, and who has appropriate qualifying expertise in laboratory animal medicine (demonstrated either by certification from the American College of Laboratory Animal Medicine, or by other evidence of expertise determined by OPRR to be satisfactory);

c. at least one practicing scientist experienced in research involving animals;

d. at least one member whose primary vocation is in a nonscientific area; and

e. at least one individual who is not otherwise affiliated with the institution and is not a member of the immediate family of a person who is affiliated with the institution.

Changes in the membership of the ARC must be reported promptly to OPRR.

B. Functions of the Animal Research Committee

The Animal Research Committee (ARC) will be the principal advisory group on humane care and use of animals to the institution and to researchers who use animals. The ARC is the appropriate body for resolving concerns involving the care and use of animals brought to the attention of the committee by veterinarians, researchers, animal caretakers or others. As necessary, the ARC will recommend to the responsible institutional official and other appropriate institutional officials, changes and improvements regarding the institution's animal program or facilities. Annual reports to OPRR (required under Option 2 only) must include any committee recommendations as forwarded to the responsible institutional official.

The ARC or the ARC Doctor(s) of Veterinary Medicine in conjunction with the ARC must be prepared to alter or to suspend a research activity whenever either of them determines that the activity is not in compliance with this policy. The ARC has responsibility to terminate the research activity if it determines that the activity cannot be brought into compliance with this policy.

In the conduct of its duties, the ARC at a minimum shall:

1. review annually the institution's program for humane animal care and use;

2. inspect annually all of the institution's animal facilities, including satellite facilities;

3. review and approve the care and use of animals as set forth in applications or proposals when PHS funds are requested (see C. Review of PHS Research Applications and Proposals);

4. review and approve proposed changes in ongoing research funded by PHS which introduce significant concerns regarding the use of the animals involved, or when animal studies were not originally proposed and approved by the ARC; and

5. when requested by PHS, review specific animal welfare issues identified during the PHS review process.

C. Review of PHS Research Applications and Proposals

Review and approval of the care and use of animals as set forth in all applications or proposals is required. However, unless one of the categories listed below pertains, the review may be conducted by the chairperson of the ARC, or another member of the ARC designated by the chairperson and qualified to conduct the review.

The care and use of animals as set forth in applications and proposals must be reviewed at a convened meeting of at least a majority of the full membership of the ARC and must be approved by a majority of the full membership whenever a research activity would:

1. include the use of nonroutine or harmful invasive procedures; or

2. include prolonged restraint; or

3. require the use of animals that have a serious natural or experimental disease and which would be maintained in that state for an extended period of time; or

4. propose methods of euthanasia that differ from those recommended by the American Veterinary Medicine Association (AVMA) Panel on Euthanasia[3]; or

5. involve any animal procedure or use which is stipulated by the ARC or by OPRR as requiring ARC review and approval.

The ARC shall approve the application or proposal only when the care and use of animals has been reviewed and found to comply with this policy and with the conditions of the institution's assurance. The ARC may not have a member participate in the ARC's review or approval of a project in which the member has a conflicting interest (e.g., the principal investigator for the project), except to provide information requested by the ARC.

An ARC may invite ad hoc technical consultants with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the ARC. These ad hoc consultants may not vote with the ARC.

Verification of approval by the ARC shall be indicated by the signature of the responsible institutional official on the face page of the application or proposal. OPRR will ask institutions that do not have an acceptable assurance on file to submit verification of approval after the institution has complied with an OPRR request to submit an assurance and establish an ARC (see D. Information Required in Applications and Proposals Submitted to PHS).

D. Information Required in Applications and Proposals Submitted to PHS.

1. All Institutions

Applications and proposals submitted to PHS that involve the care and use of laboratory animals shall contain the following information:

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[3]Journal of the American Veterinary Medical Association (JAVMA), 1978, Vol. 173, No. 1, pp. 59-72.

a. identification of the species and number of animals to be used;

b. rationale for involving animals, and for the appropriateness of the species and numbers to be used;

c. a complete description of the proposed use of the animals;

d. assurance that discomfort and injury to animals will be limited to that which is unavoidable in the conduct of scientifically valuable research, and that analgesic, anesthetic, and tranquilizing drugs will be used where indicated and appropriate to minimize discomfort and pain to animals; and

e. if euthanasia is to be involved, a description of the method to be used.

2. Institutions Which Have an Acceptable Assurance

Applications and proposals involving animals from institutions with an acceptable assurance on file with OPRR shall contain verification of approval by the ARC, indicated by the signature of the responsible institutional official on the face page of the application or proposal. PHS will consider applications or proposals incomplete if they lack verification of approval. If verification of approval is not received at the time of submission to PHS of a grant application or contract proposal, the application or proposal may be returned to the institution.

3. Institutions Which Do Not Have an Acceptable Assurance

Applications and proposals involving animals from institutions that do not have an acceptable assurance on file with OPRR shall contain a declaration that the institution will establish an ARC and submit an assurance upon request by OPRR. After such assurance has been accepted by OPRR, the ARC (or appropriate ARC member) shall review and approve the care and use of animals in the research. The responsible institutional official must submit, by letter, verification of approval of the proposed care and use of animals in the research by the ARC before an award will be made.

E. Recordkeeping.

The awardee institution shall maintain:

1. an Animal Welfare Assurance approved by the PHS;

2. minutes of ARC meetings, including records of attendance, activities of the committee, and committee deliberations;

3. records of applications, proposals and proposed changes in ongoing research reviewed and approved or disapproved;

4. records of ARC recommendations as forwarded to the responsible institutional official; and

5. records of accreditating body determinations.

All records shall be maintained for at least 3 years. Records that directly relate to applications, proposals, and proposed changes in ongoing research reviewed and approved by the ARC shall be maintained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized OPRR or other PHS representatives at reasonable times and in a reasonable manner.

V. IMPLEMENTATION BY PHS

A. Responsibilities of the OPRR.

OPRR is responsible for the general administration and coordination of this policy and will:

1. request and approve Animal Welfare Assurances and related reports;

2. distribute to executive secretaries of initial review and technical evaluation groups, and to PHS awarding units, lists of institutions that have filed an acceptable Animal Welfare Assurance;

3. advise awarding units and awardee institutions concerning the implementation of this policy; and

4. evaluate allegations of noncompliance with this policy.

B. Responsibilities of PHS Awarding Units

PHS awarding units may not make an award for a project involving animals unless the institution submitting the application or proposal is on the list of institutions that have an acceptable assurance on file with OPRR, and the responsible institutional official has provided verification of approval by the ARC. If an institution is not listed, the awarding unit will ask OPRR to negotiate an assurance with the institution before an award is made. No award shall be made until the assurance has been submitted by the institution, accepted by OPRR, and the responsible institutional official has provided verification of approval, by the ARC, of the care and use of animals as set forth in the application or proposal.

No initial, competing continuation, or recompeting award will be made if the application or proposal does not satisfy the terms of this policy.

C. Conduct of Special Reviews/Site Visits

Each awardee institution is subject to a special review, which may include a site visit, when questions are raised regarding its compliance with this policy. Institutions covered by Option 2 may be selected at random for site

visits by PHS staff and advisors to assess the adequacy of compliance with their assurance, but institutions that are covered by Option 1 will not be subject to such random site visits.

D. Waiver

Institutions may request a waiver of a provision or provisions of this policy by submitting a request to OPRR. No waiver will be granted unless sufficient justification is provided and the waiver is approved in advance and in writing by OPRR. In any event, such waivers will be granted only in exceptional circumstances.

☆ U.S. GOVERNMENT PRINTING OFFICE: 1984-421-144:2

NIH Guide
for Grants and Contracts

U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES

Vol. 13, No. 6, April 27, 1984

IN THIS ISSUE:

The NIH Guide is published at irregular intervals to announce scientific initiatives and to provide policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in grants and contracts activities administered by the National Institutes of Health.

Two types of supplements are published by the respective awarding units. Those printed on yellow paper concern contracts: solicitations of sources and announcement of availability of requests for proposals. Those printed on blue paper concern invitations for grant applications in well-defined scientific areas to accomplish specific program purposes.

Have You Moved?
If you present address differs from that shown on the address label, please send your new address to: Grants and Contract Guide Distribution Center, National Institutes of Health, Room B3BN10, Building 31, Bethesda, Maryland 20205, and attach your address label to your letter. Prompt notice of your change of address will prevent your name from being removed from our mailing list.

ERRATUM

NOTICE

INTERNATIONAL NUCLEIC ACID SEQUENCE COMPENDIUM AVAILABLE

P.T. 32; K.W. 1200920, 1201190, 1200490, 1004008

A line was omitted in the first paragraph of the above cited Notice published in the NIH Guide for Grants and Contracts Vol. 13, No. 4, March 30, 1984. The text of the corrected paragraph should read as follows:

> Nucleotide Sequences 1984, the first international compendium of nucleic acid sequences, will be published as a supplement to the May 1984 issue of Nucleic Acids Research. The compendium, which represents the databases of GenBank(tm), the Genetic Sequence Data Bank, and the European Molecular Biology Laboratory (EMBL) Nucleotide Sequence Data Library, contains information on over 4000 nucleic acid sequences, representing nearly 3 million base pairs. This includes virtually all sequences reported between 1967 and late 1983.

NOTICE

SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM

P.T. 34, 14; K.W. 0701029, 0404000, 0404001, 0404003, 0414000, 0502002, 0502011, 1200080

NATIONAL INSTITUTES OF HEALTH

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

I. FUTURE RECEIPT DATES FOR SBIR APPLICATIONS

Effective August 1984, there will be three dates a year for the receipt of SBIR grant applications. These dates will be August 15, December 15 and April 15. Both Phase I and Phase II applications will be accepted on any of these dates, provided that the Phase II application is submitted by a small business that has completed a Federally funded Phase I.

II. NO-COST TIME EXTENSIONS

No-cost time extensions to complete the Phase I effort are permissible. However, no application may be submitted for Phase II support until the Phase I project is completed. Requests for such extensions must be made in writing to and approved by the Grants Management Officer of the awarding component. Requests must state the reason(s) for the extension and be submitted before the expiration of the Phase I budget period.

III. UNOBLIGATED GRANT FUNDS AT CONCLUSION OF PHASE I

Unobligated (unspent) funds remaining at the end of a Phase I budget period of an NIH SBIR grant will not be carried over to or used as an offset (deduction) against a Phase II grant. ADAMHA will generally follow the same policy with respect to unobligated balances.

ADDENDUM TO NIH GUIDE FOR CONTRACTS AND CONTRACTS

VOL. 13, NO. 4, MARCH 30, 1984

ANNOUNCEMENT

STUDIES ON OBESITY

P.T. 34; K.W. 1200930, 0202022, 1200460, 1002019, 1200890, 0404000

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISEASES
NATIONAL CANCER INSTITUTE
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE
NATIONAL INSTITUTE ON AGING
NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT
NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE
NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM
NATIONAL INSTITUTE ON DRUG ABUSE
NATIONAL INSTITUTE OF MENTAL HEALTH

Please add to the list of institutes and individuals to be contacted for further information the following:

NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

Tina Vanderveen, Ph.D.
Chief, Clinical and Psychosocial Branch
National Institute on Alcohol Abuse and Alcoholism
Parklawn Building - Room 14C-17
5600 Fishers Lane
Rockville, Md. 20857 (301) 443-4223

NATIONAL INSTITUTE ON DRUG ABUSE

Theodore Pinkert, M.D., J.D.
Clinical and Behavioral Pharmacology Branch
Clinical Research Division
National Institute on Drug Abuse
Parklawn Building - Room 10A16
5600 Fishers Lane
Rockville, Md. 20857 (301) 443-1263

NOTICE

HEALTH SCIENTIST ADMINISTRATOR TRAINING THROUGH THE GRANTS ASSOCIATE PROGRAM

P.T. 44; K.W. 1200180, 0901026

PUBLIC HEALTH SERVICE

Scientists in health research interested in an administrative career with Federal programs supporting research, training, and services in health-related fields may wish to consider the Grants Associates Program of the U.S. Public Health Service (PHS). The program is governed by the Grants Associates Board and is administered by the Office of Extramural Research and Training (OERT), Office of the Director (OD), National Institutes of Health (NIH).

The program prepares each Grants Associate for a responsible position in health science administration in the Federal government. For a 12-month period, the Grants Associate participates in an individually structured training experience including on-the-job assignments, courses, and seminars. The program provides opportunities for participation in the development and administration of policies in Federal support of health related research, and in the fundamentals of effective management. The program also attempts to develop a sensitivity to the consequences of program decisions on other Federal health programs, research institutions, and national health needs.

Admission to the program is very highly competitive for the few positions available per year. Motivation for a career in science administration, good interpersonal skills, and evidence of executive potential are important. If you are a U.S. citizen and hold a doctorate or equivalent in a discipline related to the biomedical or behavioral sciences, have significant independent research experience beyond the doctorate (but need not have administrative experience) and are attracted to health science administration as a profession, you should inquire about the Grants Associates Program.

Grants Associates must be appointed from a U.S. Office of Personnel Management registered at grade levels General Schedule (GS) 12 ($30,402), GS-13 ($36,152), or GS-14 ($42,722).

The NIH does not discriminate in employment on grounds of race, color, sex, national origin, age, religion or handicap.

For further information write to:

Director
Grants Associates Program
Office of Extramural Research and Training
Building 31 - Room 1B-55Z
National Institutes of Health
Bethesda, Maryland 20205

NOTICE

RELEASE OF SUMMARY STATEMENTS

P.T. 22, 34, 44; K.W. 1014002

**ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION
NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM
NATIONAL INSTITUTE ON DRUG ABUSE
NATIONAL INSTITUTE OF MENTAL HEALTH**

The Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) has established procedures whereby each awarding Institute will send research and research training grant, fellowship, and cooperative agreement application summary statements, with priority scores, to the principal investigators (PIs) and program directors (PDs) promptly following Initial Review Group (IRG) meetings and before the subsequent National Advisory Council meetings.

PIs and PDs have been receiving summary statements through two procedures. Summary statements have been available through Privacy Act requests, under which they have been provided without priority scores when requested prior to Council meetings. They have also been sent automatically following the Council meetings, at which time the priority scores were displayed.

The new procedures for release of summary statements with priority scores will be effective with applications assigned to the September 1984 round of National Advisory Council meetings. Awarding components will thereupon discontinue the routine practice of sending IRG summary statements to PIs and PDs after Council meetings. Additional communications regarding Council action will be sent only when necessary (e.g., change in IRG recommendation).

Applicant investigators should address all inquiries regarding review to the Executive Secretary whose name appears on the summary statement. Inquiries on funding prospects and resubmission procedures should be directed to appropriate program officials.

NOTICE

NIH/FDA REGIONAL WORKSHOPS-PROTECTION OF HUMAN SUBJECTS

P.T. 42; K.W. 0701028

NATIONAL INSTITUTES OF HEALTH
FOOD AND DRUG ADMINISTRATION

The National Institutes of Health (NIH) and the Food and Drug Administration (FDA) are sponsoring a series of workshops on responsibilities of researchers, institutional review boards, and institutional officials for the protection of human subjects in biomedical and behavioral research. The workshops are open to everyone with an interest in research. The meetings should be of special interest to those persons currently serving or about to begin serving as a member of an Institutional Review Board (IRB).

For specific program and registration information, contact one of the individuals listed below or write to:

Roberta H. Garfinkle
Office for Protection from Research Risks
National Institutes of Health
Building 31 - Room 4B09
9000 Rockville Pike
Bethesda, Maryland 20205

NIH/FDA REGIONAL WORKSHOPS FY 1984

DATE	LOCATION	CONTACT
April 9	The Hyatt Regency New Orleans 500 Poydras Plaza New Orleans, Louisiana 70140 Telephone: (504) 561-1234	Dr. William Gibson Chairman, IRB Office for Research LSU School of Dentistry 1100 Florida Avenue New Orleams, Louisiana 70119 Telephone: (504) 948-8526
April 25	Sheraton Inn 36th and Chestnut Streets Philadelphia, Pennsylvania 19104 Telephone: (215) 387-8000	Ms. Ruth Clark Research Administrator University of Pennsylvania 3451 Walnut Street Philadelphia, Pennsylvania 19174 Telephone: (215)898-7293

April 27	Mariott Inn 4277 W. 150th Street & I-71 Cleveland, Ohio 44135 Telephone: (216) 252-5333	Dr. Dale Cowan Clinical Professor of Epidemiology and Community Health Department of Oncology Marymount Hospital 12300 McCracken Road Garfield Heights, Ohio 44125 Telephone: (216) 581-0500
May 1	Dana Farber Cancer Institute 44 Binney Street Boston, Massachusetts 02115	Mrs. Joan Rachlin Executive Director Public Responsibility in Medicine and Research (PRIM&R) 132 Boylston Street Boston, Massachusetts 02116 Telephone: (617) 423-4112 or 423-1099
May 11	Cherry Creek Inn Conference Center 600 South Colorado Blvd. Denver, Colorado 80222 Telephone: (303) 757-3341	Ms. Beverly Childress Director, Office for Continuing Medical Education University of Colorado Health Sciences Center 4200 E. Ninth Avenue, C-295 Denver, Colorado 80262 Telephone: (303) 623-2069
May 21-22	Sheraton-Midway Hotel 400 N. Hamline St. Paul, Minnesota 55104 Telephone: (612) 642-1234	Dr. Jane Boyajian President Work Ethics 2023 Milwaukee Avenue Minneapolis, Minnesota 55404 Telephone: (612) 623-2069 or Ms. Elaine S. Levine Coordinator,IRB St. Paul Ramsey Medical Center 640 Jackson St. Paul, Minnesota 55101 Telephone: (612) 221-2757
September (First or Second Week)		Ms. Phyllis S. Hall Human Subjects Coordinator Stanford University Encina Hall Stanford, California 94305 Telephone: (416) 497-3638

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA 84-CA-11

OBESITY AND CANCER RISK IN WOMEN

P.T. 34; K.W. 1200930, 1002014, 0411005, 1200790, 0701013, 0202022

NATIONAL CANCER INSTITUTE

Application Receipt Date: July 27, 1984

I. BACKGROUND

Obesity has been consistently associated with risk of endometrial cancer. Epidemiologic studies of breast cancer suggest that obesity may be associated with breast cancers, especially those diagnosed during post-menopausal years. Some other neoplasms have been related to obesity in women, such as renal carcinoma. These studies have generally used simple measures of fatness, such as weight at various ages, or height/weight ratios which may not be accurate indices of body fat for short women. Fat distribution varies and recent reports indicate that risk of diabetes is increased in women with a "masculine" fat distribution. Cancer epidemiologic studies have not considered body fat distribution in relation to risk of specific cancers.

It is known that androstenedione, a steroid hormone of adrenal origin, is converted to estrogen in the adipose tissue of post-menopausal women and that the amount of estrogen produced in this way is higher in obese women than in thin women. It has been postulated that this extra-ovarian estrogen production explains part of the association between obesity and hormone-dependent cancers of women. Some epidemiologic studies have assessed androstenedione levels as well as blood and/or urine levels of estrogens, prolactin and progesterone in relation to breast cancer risk. The possible contribution of other endocrine substances or of enzymes has received much less attention and none of these has been studied specifically with a view to understanding the relationship between obesity and cancer risk.

In summary, although obesity may increase the risk of certain cancers in women, the association has not been well described and is only partially understood.

This program is described in the Catalog of Federal Domestic Assistance No. 13.393, Cancer Cause and Prevention Research. Awards are under authorization of the Public Health Service Act, Section 301(c) and Section 402 (Public Law 78-410, as amended; 42 USC 241; 42 USC 282) and administered under PHS grant policies and Federal Regulations, most specifically at 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to Health Systems Agency Review.

II. GOALS AND SCOPE

The objective of this RFA is to stimulate research to elucidate the nature of the association between obesity and cancer risk in women, including the development of new research methods which may enhance the understanding of pertinent metabolic processes or improve the measurement of informative parameters. Research questions of interest include, but are not limited to, the following examples: (1) Is the association causal? If not, what other factors might explain the observed associations between obesity and increased risk of certain cancers? (2) Is the association with obesity related to certain forms of body fat distribution? (3) Is the association explained by the conversion of adrenal hormones to estrogen, or are more complex metabolic, hormonal or enzymatic processes involved? (4) How do diet and physical activity relate to obesity and cancer risk? (5) What parameters are informative for studies of obesity and cancer risk and how can their measurement be improved? (6) Is the mobilization of fat associated with cancer risk (as by the release of substances stored in adipose cells) either in association with lactation, weight loss, or change in hormonal status? (7) How do individuals differ in the conversion of dietary constituents to adipose tissue and how do these differences relate to cancer risk?

Responses to this RFA may be analytic epidemiologic studies, biochemical epidemiologic investigations, experimental studies in humans, or pilot/feasibility studies.

III. MECHANISM OF SUPPORT

This RFA will use the traditional National Institutes of Health (NIH) research project grant. Responsibility for the planning, direction and execution of the proposed research will be solely that of the applicant. The total project period for applications submitted in response to the present RFA should not exceed five years. The intent is to fund about five individual research project grants, with total costs amounting to approximately $0.5 million for the first year. This funding level is dependent on the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the the National Cancer Institute (NCI), the award of grants pursuant to this RFA is also contingent upon the availability of funds for this purpose. Renewal applications will compete with all other unsolicited applications received by the NCI. NIH policies governing regular research project grants, including cost sharing, apply to applications received in response to this request.

IV. COPIES OF THE RFA MAY BE OBTAINED FROM:

Dr. Genrose D. Copley
Extramural Programs Branch
Epidemiology and Biostatistics Program
Division of Cancer Etiology
National Cancer Institute
Landow Building - Room 8C-16
Bethesda, Maryland 20205

Telephone: (301) 496-9600

ANNOUNCEMENT

REQUEST FOR AVAILABILITY FOR APPLICATIONS: RFA

84-AI-07

PROGRAM PROJECTS ON THE BIOLOGY OF THE IMMUNE SYSTEM

P.T. 34; K.W. 1002004, 1002008, 1002023, 1200010, 1200060, 1200610, 1200620, 1200630, 1200660, 1200820

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Application Receipt Date: August 1, 1984

I. BACKGROUND INFORMATION

The Immunobiology and Immunochemistry Branch of the Immunology, Allergic and Immunologic Diseases Program of the National Institute of Allergy and Infectious Diseases (NIAID), supports fundamental studies on the structure and function of the immune system to gain an understanding of the immune response mechanisms at their basic cellular and molecular levels as they function in health and disease. Program Projects on the Biology of the Immune System are intended to expand the scope of, and eventually replace, the current Program Projects in Lymphocyte Biology which utilize an integrated multidisciplinary approach for basic biologic studies of immunologically-functional lymphocyte populations. Seven such program projects are currently funded although support for one is scheduled to conclude in 1985. This request for applications (RFA) is intended to encourage the development of applications from collaborating investigators and to coordinate the submission and review of new and renewal program project applications.

II. RESEARCH GOALS AND SCOPE

The goals of these Program Projects are the attainment of a complete understanding of the structure and function of the immune system and its products, its interaction with other body systems, and full knowledge of the genetic and other factors which regulate its development and function. An ultimate practical application of this information is the use of selected cloned cells of the system or their products for the clinical care or reconstitution of immunodeficient individuals, to alleviate allergic states, to provide resistance to life-threatening infections and to correct aberrant or defective immunoregulatory mechanisms.

The scope of these program projects includes studies of every facet of the immune response, ranging from the initial step of antigen recognition to the final elaboration of immunologically distinctive products of specific immunocytes. Research currently supported by this mechanism was designed to greatly expand knowledge of the morphologic and functional heterogeneity of lymphocyte populations and to develop the capability for identification and selection of lymphocyte subpopulations with specific immune reactivity or antigenic

composition, for hybridization of such populations and for selective production of specific, biologically-active, lymphocyte products. Continuation of such studies is anticipated and appropriate, as are similar studies of macrophages, other accessory and effector cells, and activation, differentiation and regulation of the immune system. Also relevant are investigations on interactions and influences of other body systems with the immune system.

III. MECHANISM OF SUPPORT

Program project grants are awarded to an institution on behalf of a program director for the support of a broadly based, multidisciplinary, long-term research program which has a specific major objective or basic theme. A program project generally involves the organized efforts of groups of investigators, members of which conduct research projects related to the overall program objective. The grant can provide support for the projects and for certain core resources shared by individuals in a program where the sharing facilitates the total research effort. Each component project supported under a program project grant is expected to contribute to and be directly related to a common theme; the projects should demonstrate an essential element of unity and interdependence.

IV. STAFF CONTACT

A more detailed RFA may be obtained from:

John F. Finerty, Ph.D.
Immunobiology and Immunochemistry Branch, IAIDP
National Institute of Allergy and Infectious Diseases
Westwood Building - Room 757
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-7551

Prospective applicants are encouraged to submit a one-page letter of intent that includes a brief synopsis of the proposed research and identification of any other participating institutions. The Institute requests such letters by June 1, 1984, for the purpose of providing an indication of the number and scope of applications to be received. A letter of intent is not binding. It will not enter into the review of any application subsequently submitted and is not a necessary requirement for application. Letters of intent and inquiries should be directed to Dr. Finerty at the address shown above.

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

84-HL-14P

MINORITY SUMMER PROGRAM IN PULMONARY RESEARCH

P.T. 44; K.W. 1200170, 1201210

DIVISION OF LUNG DISEASES

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: August 15, 1984

The Division of Lung Diseases, National Heart, Lung, and Blood Institute (NHLBI) announces the availability of a request for applications (RFA) for a summer training program in pulmonary research. The objective of this program is to provide opportunities for minority school faculty members and graduate students to gain experience and exposure to ongoing pulmonary research projects in established pulmonary training centers.

Training grants will be awarded to pulmonary training centers for a 5 year period. Trainee participation in a program will be for one or more summers, and total support for any individual may not exceed 9 months. Trainees will be selected by a joint panel which will be composed of members from the pulmonary training center and from the minority school(s).

A review group convened by Division of Extramural Affairs (DEA) NHLBI, will review all applications. This will be followed by a second level of review by the National Heart, Lung, and Blood Advisory Council in February 1985. The earliest start date is May 1985.

Inquiries regarding this announcement may be directed to the program administrator:

Research Training and Development Officer
Prevention, Education and Manpower Branch
Division of Lung Diseases
National Heart, Lung, and Blood Institute
National Institutes of Health
Westwood Building - Room 6A12
Bethesda, Maryland 20205

Telephone: (301) 496-7668

This program is described in the Catalog of Federal Domestic Assistance, No. 13.838, Lung Disease Research. Awards will be made under the authority of the Public Health Service Act, Section 472,42 USC 2891-1, and administered under the PHS grant policy and Federal Regulations 42 CFR Part 66. This program is not subject to Health Systems Agency Review.

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

84-NS-01

MULTIDISCIPLINARY RESEARCH CENTER(S) FOR THE STUDY OF THE NEUROLOGICAL BASIS OF DISORDERS OF LANGUAGE, BEHAVIOR AND LEARNING DURING INFANCY AND EARLY CHILDHOOD

P.T. 04, 34; K.W. 1200220, 1200180, 0404004, 0414000, 1200380, 1201010, 0701038

NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE - IN COSPONSORSHIP WITH THE NATIONAL INSTITUTE OF MENTAL HEALTH

Application Receipt Date: October 1, 1984

I. PROGRAM OBJECTIVES AND SCOPE

The NINCDS, in cosponsorship with the NIMH, intends to establish a multidisciplinary center(s) to conduct investigations of both a clinical and basic nature aimed at determining patterns of brain development and function in language, behavior, and learning disorders during infancy and early childhood. Investigators are encouraged to assemble multidisciplinary investigative expertise in appropriate fields to conduct such research. Infants and children may manifest specific problems in language, learning and behavior or in association with a serious disease or syndrome. Differences in brain development across the spectrum of normal development, specific disorders of language, behavior and learning and in serious diseases and syndromes need to be examined.

Advancing technologies in neuroimaging present new investigative opportunities. Neuroanatomic studies utilizing NMR are desirable to relate to the results of behavioral investigations in various disordered groups for examining brain-behavior relationships. Neurophysiological studies employing such techniques as positron emission tomography during rest and during specific task-oriented activity might be aimed at understanding brain-behavior relationships in those cases with serious diseases and syndromes. Adults with persistent residual developmental disorders may also be appropriate subjects for positron emission tomography studies during syndrome-specific task challenges. When appropriate, histopathological studies of brains made available through autopsy (including neurochemical studies of fresh brain tissue) would provide correlative data as well as a strong basic research component leading to a better understanding of the relationships between patho-physiology and language, behavior, and learning disorders. When effective treatment is being sought for some serious diseases and syndromes, neuropharmacologic trials may be justified. For example, neurochemical effects on brain metabolism and language functioning may be studied to determine how language learning is changed by neuropharmacologic modification of brain function. Experimental learning studies, studies, as another example, could examine the differences in language, learning, and behavior occurring in different

patterns of brain development and in different brain dysfunction disorders. Similar studies of attention, perception, memory, and communicative and motor skills could also be addressed.

When children with serious neurological or neuropsychiatric diseases and syndromes undergo diagnostic procedures for their own medical benefit and such children manifest well-defined learning, behavior and language disorders in the context of serious diseases or syndromes, a rare opportunity presents for intensive study of brain mechanisms not permissible in children with less serious handicaps. Studies of language, behavior and learning in children with serious diseases and syndromes would be supported as one end of the investigative spectrum.

II. ELIGIBILITY

For-profit and non-profit organizations or institutions in the U.S. are eligible to apply. Applications will be reviewed for scientific and technical merit by an NINCDS special review committee and for program relevance by the National Advisory Neurological and Communicative Disorders and Stroke Council, and in cases of joint support with NIMH, by the National Advisory Mental Health Council.

III. MECHANISM OF SUPPORT

Awards will be made as research grants. The total project period for applications submitted in response to the present RFA should not exceed five years.

IV. ANTICIPATION OF NUMBER OF AWARDS

The NINCDS, in cosponsorship with the NIMH, intends to fund up to two research centers for an initial period of up to five years. The NINCDS has a maximum direct cost guideline of $600,000 per year on any award action.

V. APPLICATION RECEIPT DATE

Applications prepared on Form PHS 398 must be received in the Division of Research Grants (DRG) NIH, on or before October 1, 1984.

VI. REQUEST FOR COPIES OF RFA AND INFORMATION

To obtain a copy of the RFA and/or for further information please contact:

Joseph S. Drage, M.D.
Chief, Developmental Neurology Branch
Convulsive, Developmental, and Neuromuscular
Disorders Program
National Institute of Neurological and
Communicative Disorders and Stroke
Federal Building - Room 816
Bethesda, Maryland 20205

Telephone: (301) 496-6701

ANNOUNCEMENT

RESEARCH IN SICKLE CELL DISEASE: PAIN MANAGEMENT IN SICKLE CELL DISEASE

P.T. 34; K.W. 1200240, 1200080, 0701036, 0414003, 1200120, 1200270

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: July 1, November 1, March 1

The National Heart, Lung, and Blood Institute (NHLBI), Division of Blood Diseases and Resources, supports programs designed to reduce the mortality and morbidity of sickle cell disease by improving diagnostic and treatment methodologies and providing resources for biomedical research, both at the basic and clinical levels.

The purpose of this program announcement is to encourage well-conceived research efforts to investigate alternative approaches to the treatment and/or prevention of painful episodes. These painful episodes occur throughout the patient's life and constitute the major reason for seeking medical care. Presently, there is no specific treatment for painful episodes, and management is limited to symptomatic and supportive measures which are frequently unsatisfactory and frustrating to both the patient experiencing the pain and to the physician who can only help through increasing analgesic administration with attendant concern about increasing the risk of drug dependence.

To date, there has been little information related to effective pain management in this disease reflecting perhaps the problems surrounding effective pain management in general. Similarly, techniques of drug administration and dose delivery have not changed significantly over the past several decades, even though investigators have repeatedly addressed the inadequacies inherent in conventional analgesic regimens. Therefore, we wish to stimulate research studies to evaluate more effective management of pain in this disease.

The NHLBI encourages interested investigators to submit research grant applications to investigate the effectiveness of alternative behavioral modalities for pain management and/or document the pharmacokinetics and bioavailability of analgesics in sickle cell disease patients.

Potential studies might involve documentation of the ability of various self-regulatory techniques to: (a) reduce the frequency, severity, and duration of painful episodes; and

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This program is described in the Catalog of Federal Domestic Assistance No. 13.839, Blood Diseases and Resources. Grants will be awarded under the authority of the Public Health Service Act, Section 301 (42USC 241) and administered under PHS grant policies and Federal Regulations, most specifically at 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to Health Systems Agency review.

(b) change pain-related behavior, i.e., the frequency of emergency room visits, the frequency and length of hospital admissions, absenteeism, and the use of analgesics. Specifically, evaluation of the use of relaxation techniques, self-hypnosis, guided imagery, cognitive behavior modification, and other self-regulatory techniques are encouraged as treatments or adjuncts to pharmacological agents of pain management. It is anticipated that proposals will reflect interdisciplinary research teams involving algologists or behavioral specialists, as well as the primary care physicians providing care and support for the patients.

Support for this research is available through investigator initiated research grants. Application receipt dates are July 1, November 1, and March 1. Applications should be submitted on form PHS 398; these forms are available in the business or grants and contracts office at most academic and research institutions or from the Division of Research Grants (DRG) NIH. In order to identify the application as a response to this announcement, check "yes" on Item 2 of the application face page with the title **PAIN MANAGEMENT IN SICKLE CELL DISEASE.** The original and six copies should be submitted to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

Other PHS components share interest in studies of pain management. Applications received in response to this Program Announcement will be assigned by the DRG. Assignment for program responsibility and funding will be according to established referral guidelines; assignment for review will be to study sections according to the NIH process for regular research grant applications. Funding for this activity is in competition with all regular competing grant applications.

Requests for additional information or questions regarding this program should be directed to

Marilyn H. Gaston, M.D.
Sickle Cell Disease Branch
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
Federal Building - Room 504
7550 Wisconsin Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-6931

or

Dr. Katrina Johnson
Behavioral Medicine Branch
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
Federal Building - Room 604
7550 Wisconsin Avenue
Bethesda, Maryland 20205

Telephone: (301)-496-9380

ANNOUNCEMENT

TRANSFUSION MEDICINE ACADEMIC AWARD

P.T. 10, 34, 44; K.W. 1200170, 1200180, 1200200, 0502024

DIVISION OF BLOOD DISEASES AND RESOURCES

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: October 15, 1984

The Transfusion Medicine Academic Award (TMAA) was initiated in January 1983, to (1) encourage the development of curricula in transfusion medicine, and (2) allow the awardee to broaden his or her expertise in transfusion medicine so as to contribute more effectively to the teaching, research, and clinical needs of this discipline. The term "transfusion medicine" is used to define a multidisciplinary area concerned with the proper use or removal of blood and its components in the treatment or prevention of disease states (other than in renal hemodialysis). Each school of medicine or osteopathy in the United States or its possessions and territories is eligible for one 5-year TMAA (nonrenewable) which provides salary, fringe benefits, supporting costs, and indirect costs to well-trained investigator-faculty members who are skilled organizers and negotiators. The number of awards made each year will depend on the availability of funds.

The Division initiated the TMAA program to encourage the development of teaching programs in transfusion medicine. At present, teaching, research, and clinical responsibilities in transfusion medicine are rarely coordinated into a definable program but are dispersed among basic and clinical science disciplines and among activities of the local transfusion services or blood center facility. It is important to note that establishing a transfusion medicine curriculum may not require additional curriculum time; existing teaching materials (components of other disciplines) may be coordinated into an overall program and organized to focus on emerging and important areas of transfusion medicine. Some schools may find it desirable to assemble the appropriate components into a specific unit. Others may wish to retain the transfusion medicine discipline as part of another major clinical or laboratory department.

The program is described in the Catalog of Federal Domestic Assistance No. 13.839, Blood Diseases and Resources. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (42 USC 241) and administered under PHS grant policies and Federal regulations, most specifically 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to Health Systems Agency Review.

This award is also intended to:

- attract to the field of transfusion medicine outstanding students and promising young physicians and scientists who can serve the teaching, research, and clinical aspects of transfusion medicine;

- encourage the development of faculty capable of providing appropriate instruction in the field of transfusion medicine;

- facilitate interchange of information, and evaluation and educational techniques among research, medical, and blood service communities; and

- enable the grantee institution to develop a continuing transfusion medicine program, using local support, when this Award terminates.

Applications must be received by October 15, 1984, for review at the May 1985 meeting of the National Heart, Lung, and Blood Advisory Council. Awards will be made in September 1985, depending on the availability of funds. Requests for the TMAA Program Guidelines should be directed to:

Fann Harding, Ph.D.
National Heart, Lung, and Blood Institute
Federal Building - Room 5A08
Bethesda, Maryland 20205

Telephone: (301) 496-1817

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